Office of Civilian Radioactive Waste Management QA: QA

QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION

DOE/RW-0333P

Revision 18

Effective Date: 10/02/2006

Michael Ulshafer, Acting Director
Office of Quality Assurance

5/31/06
Date

Paul M. Golan, Acting Director
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6/1/06
Date

Office of Civilian Radioactive Waste Management
Quality Assurance Policy

Successful implementation of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) program is essential for the OCRWM to carry out its mission.

Our mission is to manage and dispose of high-level radioactive waste and spent nuclear fuel in a manner that protects health, safety, and the environment; enhances national and energy security; and merits public confidence.

The *Quality Assurance Requirements and Description* (QARD) establishes the requirements for the OCRWM QA program designed to meet 10 CFR 63.142, Quality Assurance Criteria. The QARD also defines the organizational responsibilities related to implementation and oversight of the OCRWM QA program.

The QARD provides for both the achievement and verification of quality. The line organization has responsibility for meeting the OCRWM QA program requirements within their areas of responsibility, and individuals are responsible for the quality of their work. The line organization and the QA organization share responsibility for the verification of quality. Quality must be an important and living part of everything that we do on this project. Quality must be planned up-front to ensure that quality requirements are flowed into our implementing documents. Additionally, we need to hold ourselves to the high standards that we have set, to objectively assess our performance against these standards, and take prompt and aggressive action when we find divergence. We must learn from our mistakes, never be satisfied with our performance, and always have a questioning attitude about our work. It is only then that the QARD becomes a living document, where quality lives in the organization and becomes part of our culture.

As the Director, OCRWM, I am responsible for the OCRWM QA program; ensure its development, implementation, and verification; and retain ultimate review and approval authority on matters pertaining to the implementation of the OCRWM QA program. Organizations performing quality-affecting work for the OCRWM shall comply with the applicable requirements from the QARD. Work shall not proceed unless the work can be accomplished as described in approved procedures, instructions, and drawings. Work shall be stopped if a significant condition adverse to quality exists and the nature of the condition warrants such action.

Paul M. Golan, Acting Director
Office of Civilian Radioactive Waste Management

6/1/06
Date

REVISION HISTORY

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
18	New *Quality Assurance Requirements and Description* document developed to comply with 10 CFR 63.142 and NUREG-1804. Complete rewrite. **QARD Revision 18 Draft Chronology** This revision was processed as Revision 0, Revision 17, and Revision 18 in accordance with the following: • DOE/RW-XXXX, Revision 0, Draft A, 5/17/04 • DOE/RW-0566, Revision 0, Draft B, 8/10/04 • DOE/RW-0333P, Revision 17, Draft B, 9/9/04 • DOE/RW-0333P, Revision 17, Draft C, 2/1/05 • DOE/RW-0333P, Revision 17, Draft D, 3/7/05 • DOE/RW-0333P, Revision 17, Draft E, 3/15/05 • DOE/RW-0333P, Revision 17, Draft F, 4/1/05 • DOE/RW-0333P, Revision 17, Approved Draft F, dated 4/4/05 was submitted to the NRC for review. • DOE/RW-0333P, Revision 17, Approved Draft F, dated 4/4/05 was accepted by the NRC with conditions 8/4/06. See correspondence Reamer (NRC) to Ziegler (DOE) dated 08/04/2005. • DOE/RW-0333P, Revision 17, Draft G, 11/8/05 • DOE/RW-0333P, Revision 17, Draft H, 12/8/05 • DOE/RW-0333P, Revision 17, Draft I, 2/6/06 • DOE/RW-0333P, Revision 17, Draft J, 3/9/06 • DOE/RW-0333P, Revision 18, Draft K, 5/10/06 – This draft incorporated the “New OCRWM Organization” into DOE/RW-0333P Revision 17, Draft J, 3/9/06.	10/2/06

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Section **Title**

INTRODUCTION

The Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) program consists of the *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P and those documents that implement the QARD, (i.e., procedures, instructions, and drawings [implementing documents]).

The QARD establishes requirements for the OCRWM QA program that meets the requirements of 10 CFR 63.142, Quality Assurance Criteria, that are to be implemented for activities up to the time of receipt of high-level radioactive waste and spent nuclear fuel for disposal in the geologic repository at Yucca Mountain. The QARD will be revised as necessary at the appropriate time to include facility operation, permanent closure, and decontamination and dismantling of surface facilities.

The QARD is applicable to structures, systems, components, and related activities described in Section 2.0.

The QARD requirements are derived from regulatory and industry documents. The OCRWM commits to the staff positions and provisions as delineated in Table 1, Regulatory/Commitment Document Positions.

The QARD is organized into sections, supplements, an appendix, table, and glossary. The sections are consistent with the criteria of 10 CFR 63.142 and contain requirements that are common to all OCRWM activities. The supplements provide specific criteria relative to certain unique activities. The appendix specifies how the OCRWM will ensure that waste custodians' high-level waste and spent nuclear fuel will be acceptable for emplacement in the geologic repository. The table provides the commitments to certain specific regulatory and industry documents. The glossary establishes a common vocabulary for the OCRWM QA program.

Suppliers, and principal contractors that are contracted directly to the OCRWM, are identified as "OCRWM contractors."

The requirements of the QARD that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

QA program description documents developed by suppliers incorporate the requirements of the purchaser's QA program description document, as applicable to their scope of work. These documents are accepted by the purchaser prior to the start of work.

OCRWM contractors may work to OCRWM or a principal contractor's implementing documents when stipulated in procurement documents, in accordance with Section 4.0.

Suppliers to a principal contractor may work to OCRWM or the principal contractor's implementing documents, if permitted by the principal contractor's QA program description document and if stipulated in procurement documents.

1.0 ORGANIZATION

1.1 GENERAL

A. The Office of Civilian Radioactive Waste Management (OCRWM) organizational structure encompasses those positions responsible for establishing, managing, verifying, and interpreting the OCRWM Quality Assurance program. The *Quality Assurance Requirements and Description* (QARD) establishes the relationships of organizations within the OCRWM, including principal contractors and waste custodians with overall responsibilities for performing activities related to structures, systems, and components (SSCs) important to safety or waste isolation, and to the design and characterization of barriers important to waste isolation.

B. The QARD identifies the requirements and delineates the major authorities and responsibilities of organizations supporting the OCRWM.

1.2 REQUIREMENTS

The OCRWM and principal contractors shall prepare one or more controlled documents that describe their responsibilities and authorities, including the management positions responsible for achieving and maintaining quality, internal and external organizational interfaces, organizational structures, and responsibilities for their scope of work. These documents shall be revised upon any reorganization that impacts responsibilities associated with the implementation of QARD-related activities.

1.2.1 Responsibility for Quality

Quality shall be achieved and maintained by those who have been assigned responsibility for performing work. The achievement of quality shall be verified by persons or organizations not directly responsible for performing the work.

1.2.2 Resolution of Quality Disputes

Differences of opinion between the QA organization and other personnel involving the OCRWM QA program requirements shall be brought to the attention of the appropriate management and, if not resolved, shall be elevated progressively to successively higher levels of management. The Director, OCRWM, has ultimate resolution authority.

1.3 DESCRIPTION

A. Organization charts that clearly identify all OCRWM and principal contractor on-site and off-site organizational elements that function under the cognizance of the OCRWM QA program shall be maintained and controlled under the

OCRWM QA program (e.g., design, engineering, procurement, shipping, receiving, storage, manufacturing, construction, inspection, auditing, testing, instrumentation and control, maintenance, modification, etc.). These charts also identify lines of responsibility. Figure 1, OCRWM Organization, identifies the OCRWM organizational units responsible for the implementation of activities governed by the QARD. Figure 2, OCRWM External Interface, identifies the OCRWM interface with the principal contractors and waste custodians.

B. The OCRWM is comprised of the Office of the Director and Principal Deputy Director, Office of Quality Assurance, Office of the Chief Scientist, Office of the Chief Engineer, Regulatory Authority Office, Infrastructure Management Office, Yucca Mountain Site Operations Office, Waste Management Office, Office of Logistic Management, Disposal Operations Office, Office of Project Controls, Office of Procurement, Office of Government Services, and Office of External Affairs.

C. Any substantial OCRWM reorganization of descriptions or functions of the offices described herein will require a revision to this document.

1.3.1 Specific OCRWM Offices

A. Office of the Director/Principal Deputy Director.

The Office of the Director/Principal Deputy Director is responsible for carrying out the functions of the Secretary of Energy under the Nuclear Waste Policy Act and for providing overall management of the OCRWM Program.

The Director/Principal Deputy Director report to the Secretary of Energy through the Under and Deputy Secretaries; retains ultimate responsibility for the overall OCRWM Program; and are responsible for providing leadership in developing and implementing strategies to accomplish the OCRWM Program's mission in a manner that assures public and worker health and safety, protects the environment, merits public confidence, and is economically viable. In addition, the Director/Principal Deputy Director are responsible for licensing and approval to construct and operate a geologic repository for the safe disposal of high-level radioactive waste and spent nuclear fuel and for providing for the safe transportation of high-level radioactive waste and spent nuclear fuel to the geologic repository. Staff within the immediate Office of the Director provides advice to the Director and Principal Deputy Director and support development of the OCRWM Program policies. Several programmatic and technical authorities of the Director, OCRWM, are delegated to line management as reflected in this document.

Responsibilities and authorities that are retained by the Office of the Director/Principal Deputy Director and are not delegated are as follows:

1. Ultimate responsibility for the effective implementation of the OCRWM QA program and for revision and approval authority of the QARD.

2. Ultimate resolution authority for the resolution of quality disputes.

3. Long-term planning and facility-wide safety.

4. Mission assignments and broad OCRWM Program policy, guidance, and direction to the OCRWM management team through, among other things, the OCRWM Strategic Plan and Program Plan, Civilian Radioactive Waste Management System Major System Management Policy, and the Integrated Safety Management Plan.

5. Establishment of the OCRWM organizational structure, including the organizational roles, responsibilities, authority, and accountability for key OCRWM Program functions.

6. Ensuring that a sufficient number of trained personnel are available to implement applicable portions of the OCRWM QA program before the initiation of activities within the scope of the OCRWM QA program.

7. Integration of program activities and monitoring of key performance indicators.

8. Continuing involvement in OCRWM QA program activities by directing the performance of periodic management assessments of the OCRWM QA program and principal contractors' QA programs to determine the adequacy and effectiveness of these QA programs.

B. Office of Quality Assurance

1. Is responsible for the QA functions for the OCRWM QA program.

2. Is sufficiently independent from cost and schedule when opposed to safety considerations.

3. Has access to work areas and the organizational freedom to effectively communicate with other senior managers.

4. Has the authority to fulfill the responsibilities of the position.

5. Has no other assigned responsibilities unrelated to the OCRWM QA program that would prevent full attention to QA matters.

6. Provides guidance and direction, relative to QA matters, to identify quality problems; initiate, recommend, or provide solutions; and to verify implementation of corrective action.

7. Has the authority to stop work when significant conditions adverse to quality warrant such action.

8. Is qualified in accordance with Subsection 2.2.11.

9. Maintains liaison with OCRWM contractors and waste custodian QA organizations to remain current on the status of activities related to their QA programs.

10. Specific duties and responsibilities include the following:

    a. Assuring implementation of the OCRWM Quality Assurance Policy

    b. Assuring that the OCRWM QA program complies with regulatory and management requirements, is established consistent with the schedule for accomplishing the activities, is maintained, and is effectively executed

    c. Developing, approving, and maintaining the QARD

    d. Interpreting QA requirements established in the QARD

    e. Documenting concurrence and/or approval (as specified in applicable procedures or procurement documents) of quality-related documents used by OCRWM contractors to ensure conformance with the requirements of the QARD

    f. Verifying the adequacy and implementation (i.e., compliance and effectiveness) of the OCRWM QA program and reporting the results to OCRWM senior management

    g. Verifying the adequacy and implementation of OCRWM contractors' QA program description documents and implementing documents with the requirements of the QARD. Verification may include review of selected implementing documents as well as the use of audits, surveillance, and inspections, as appropriate

    h. Identifying quality problems; initiating, recommending, or providing solutions to quality problems; and verifying solutions to quality problems

    i. Ensuring that there is adequate quality assurance coverage relative to procedural and inspection controls, acceptance criteria, and quality assurance staffing and qualifications of personnel to carry out quality assurance assignments.

11. The quality assurance activities include quality engineering, quality verification, and OCRWM QA program and policy development.

12. OQA staff shall be involved in day-to-day OCRWM activities such as work schedule and status meetings.

13. Responsibilities are carried out through a trained staff of qualified personnel. The qualifications of the OQA staff, including direct support contractors, shall be in accordance with Subsection 2.2.11.

C. Office of the Chief Scientist

1. Coordinates all scientific research for the OCRWM Program.

2. Ensures the OCRWM Program has the best data and information possible in the performance of scientific research.

3. Manages interfaces with other Department of Energy supporting organizations including the national laboratories.

4. Serves as approving authority for all scientific information associated with the OCRWM Program.

5. Provides direction, review, and approval of contractor strategy and plan for the conduct of performance assessments.

6. Ensures technical and regulatory adequacy of post-closure safety assessment and performance confirmation results.

7. Develops guidance/requirements for the technical activities associated with identifying, evaluating, and distributing information from scientific investigations and repository performance assessment activities.

8. Identifies, evaluates, and supports scientific investigations and analyses of current and developing technologies.

D. Office of the Chief Engineer

1. Serves as Project Director for the repository.

2. Resolves all design-related project technical issues.

3. Applies scientific requirements in the development of an approach that can be constructed and operated.

4. Designs all systems and components, including aging and disposal canisters and their associated aging casks/overpacks.

5. Serves as the design authority; coordinates policy issues associated with design and nuclear safety.

6. Supports OCRWM management on design bases information for repository performance assessment.

7. Represents OCRWM in constituent interactions on repository design issues.

8. Establishes requirements and monitors the development of repository design.

9. Develops and maintains project-level requirements.

10. Establishes design-related mechanisms for DOE control and approval of repository design and operational baseline changes including designation of appropriate DOE approval levels.

11. Leads periodic DOE management reviews of design activities to ensure that workable repository design solutions are developed according to established schedules.

12. Monitors contractor design activities including the development of designs for individual features, as well as comprehensive design products.

13. Identifies and communicates to management potential design-related changes and issues that have policy and system implications.

14. Ensures technical and regulatory adequacy of design and pre-closure safety analysis results.

15. Monitors design product development for requirement compliance and reviews engineering product deliverables.

16. Ensures appropriateness of engineering solutions.

17. Performs and monitors project-level system engineering activities.

18. Provides oversight of technical data management.

19. Develops pre-closure safety and hazards analysis.

E. Regulatory Authority Office

1. Serves as Chief Nuclear Officer.

2. Provides overall direction and approves the basis for placement of items on the Q-list, including the actual placement of items on the Q-List and Management Control List for design and construction of surface and subsurface facilities.

3. Integrates design, scientific, safety analysis, and performance assessment inputs into coherent systematic descriptions to demonstrate compliance with regulatory requirements.

4. Monitors performance assessment activities, including the development of models that represent processes and events that could impact the ability of the repository to contain and isolate radioactive waste.

5. Initiates and maintains Memoranda of Understanding and Memoranda of Agreement.

F. Infrastructure Management Office

1. Constructs all aspects of the project.

2. Develops and implements a construction project acceptance and turnover program.

3. Ensures the adequacy and correctness of engineering design documentation (e.g., as built/as-constructed design drawings).

4. Verifies infrastructure system, structure and component turnover documentation.

5. Supports design and construction interface to ensure project constructability.

6. Participates in design reviews providing project construction input.

7. Serves as the infrastructure construction authority.

8. Manages and integrates all aspects of field operations including engineering, design, construction, and site testing activities.

9. Maintains site construction and operations to ensure compliance with applicable standards and reporting requirements.

10. Maintains a construction project authorization and control process to ensure that applicable Nuclear Regulatory Commission (NRC) authorizations and approvals are secured prior to initiation of field construction activities.

G. Yucca Mountain Site Operations Office

1. Manages all facilities and operations at the Yucca Mountain site.

2. Establishes, controls, and verifies site operations and maintenance requirements.

3. Establishes and oversees the safety basis for operations.

4. Establishes performance specifications, maintains and controls system, structure and component configuration for Yucca Mountain site facilities including the tunnel (as built/as-constructed design).

5. Ensures that the Yucca Mountain site facilities comply with applicable Federal, State, and local requirements.

6. Ensures compliance with radiological protection standards and regulations.

7. Monitors and oversees facility NRC governed occurrence and incident reporting.

8. Manages and oversees activities for lessons learned, benchmarking, trending and other feedback, and ensures results are incorporated as appropriate for continuous improvement.

9. Manages performance assessment to include the coordination and integration of external assessments and audits and OCRWM responses.

10. Performs line management and oversight activities for the development and implementation of objectives, policies, procedures, and plans for the Corrective Action Program (CAP), and administrator to the CAP.

11. Serves as Co-Chair for the Management Review Committee for the CAP.

12. Ensures consistent implementation and oversight of the cause analyses, corrective action plans, implementation of corrective actions, and feedback through trend reports.

13. Manages and oversees the document hierarchy process and activities for policy, procedure, plan requirement, and charter development revision, cancellation, and control.

H. Waste Management Office

1. Manages the standard contracts for disposal of spent nuclear fuel and/or high-level radioactive waste with waste custodians.

2. Designs and integrates waste packaging including transportation and storage containers.

3. Establishes requirements for waste (waste acceptance criteria) that will be shipped to Yucca Mountain.

4. Serves as the authority on transportation packages, waste packages, and waste acceptance criteria.

5. Establishes waste acceptance policy and requirements for repository and transportation projects.

6. Coordinates and maintains OCRWM Program interface with DOE Office of Environmental Management (EM); Office of Nuclear Energy (NE); National Nuclear Security Administration; and Naval Nuclear Propulsion Program (NNPP) on waste management and disposal issues pertinent to the OCRWM Program.

7. Ensures EM and NE waste acceptance quality assurance requirements are implemented.

8. Coordinates and evaluates the incorporation of EM programs into OCRWM (e.g., National Spent Nuclear Fuel Program and National Transportation Program).

9. Develops strategy, policy, requirements, and guidance for the quantities and associated sequence by which OCRWM will accept DOE owned and additional forms of radioactive waste beyond domestic commercial spent nuclear fuel and DOE high-level waste glass.

10. Develops waste acceptance criteria for DOE spent nuclear fuel and high-level waste.

11. Ensures transportation package regulatory compliance with internal and external regulatory requirements.

12. Initiates and manages performance of technical studies and alternative evaluations.

13. Ensures that changes to existing programmatic policies, plans, and procedure related requirements, are identified, evaluated, and controlled, and applicable requirements are incorporated into OCRWM Program implementing documents.

14. Develops and maintains the OCRWM Program-level technical management requirements.

15. Develops and maintains level 1 technical baseline and provides systems engineering support at the OCRWM Program level.

16. Conducts the necessary systems analyses to confirm that system-level changes are acceptable from an overall systems viewpoint and provide this to the appropriate change control boards.

17. Manages and oversees activities for configuration management of appropriate source documents (e.g., charters, plans, etc.).

18. Monitors system interfaces and integrates where necessary.

19. Coordinates OCRWM interfaces with NNPP and the National Spent Nuclear Fuel Program.

I. Office of Logistics Management

1. Provides technical requirements for procurement of casks. Coordinates with procurement on technical interchange with vendors prior to issuing Request for Proposals (RFP).

2. Establishes and implements interface control and manages transportation interfaces with external programs.

J. Disposal Operations Office

Activities performed by this office are outside the scope of QARD Rev. 18. The QARD establishes the minimum requirements for the OCRWM QA program designed to meet the requirements of 10 CFR 63.142 that are implemented for activities up to the time of receipt of high-level radioactive waste and spent nuclear fuel for disposal in the geologic repository at Yucca Mountain. The QARD will be revised as necessary at the appropriate time to include facility operation, permanent closure, and decontamination and dismantling of surface facilities.

K. Office of Project Controls

Responsible for managing the configuration control management system.

L. Office of Procurement

1. Provides centralized business management and administration of the OCRWM Management & Operating (M&O) contract, program-wide support service contracts, grants, cooperative agreements, and interagency agreements.

2. Manages OCRWM advanced acquisition planning and provides guidance on acquisition regulatory requirements, including maintenance of contractual documents required for major system acquisitions.

3. Prepares procedures governing OCRWM quality affecting acquisition instruments.

4. Assists OCRWM staff in the establishment of acquisition strategies, procurement requirements, and acquisition plans for OCRWM requirements.

5. Manages acquisition planning, RFP development, RFP evaluation, and award for OCRWM acquisition instruments.

M. Office of Government Services

1. Develops manpower requirements/allocations.

2. Verifies education and experience of applicable OCRWM personnel.

3. Manages the OCRWM training program.

4. Establishes policy for training of DOE and contractor personnel on OCRWM Program (to include quality assurance training).

5. Develops, issues, and oversees implementation of information technology policies and procedures.

6. Ensures implementation of the software management functions for mission-specific applications, including implementation of the Capability Maturity Model.

7. Ensures that the software management program complies with the requirements of Supplement I and Supplement V.

8. Ensures the development and implementation of effective records policies consistent with Section 17.0.

N. Office of External Affairs

This office does not perform any activities that are within the scope of the QARD.

O. Line Management Functions (All Office Directors)

1. Manage functions and resources and provide leadership.

2. Monitor contractor performance against approved plans and direct corrective actions when necessary.

3. Coordinate and integrate activities with appropriate OCRWM organizations.

4. Ensure that staff position descriptions are up-to-date.

1.3.2 Delegation of Authority

The Director, OCRWM, retains ultimate responsibility for the adequacy and effectiveness of the OCRWM QA program. The QA requirements applicable to OCRWM contractors shall be established and delineated in appropriate procurement documents. The QA interface between the OCRWM and waste custodians shall be established and delineated in appropriate agreement documents. The OCRWM has delegated to OCRWM contractors the work of establishing and executing an effective QA program to be applied to the geologic repository as specified in Subsection 2.2.2, as applicable to their scope of work.

1.3.3 Principal Contractors

The M&O contractor and the Lead Laboratory for Repository Systems (Lead Laboratory) are principal contractors. The transfer of responsibilities from the M&O to the Lead Laboratory shall be accomplished in accordance with an approved Transition Plan as identified in the M&O contract and Lead Laboratory agreement in accordance with Section 4.0.

A. Management and Operating Contractor

The M&O is responsible for the design, construction, and eventual operation of the Yucca Mountain Site (YMP) site. The senior manager of the M&O organization is the General Manager. The General Manager is responsible for setting and implementing policies, expectations, and priorities to ensure that the functions being performed by the M&O are in accordance with the M&O QA program. Supporting the General Manager is an organization that is responsible for performing the design and construction of the geologic repository, including providing related support. Specific M&O responsibilities are identified in the contract between the OCRWM and the M&O.

B. Lead Laboratory

The Lead Laboratory reports to the Office of the Chief Scientist and is responsible for the scientific and technical work necessary to support the preparation and maintenance of the postclosure portions of the License Application for the geologic repository, including the performance confirmation program. The senior manager of the Lead Laboratory organization is the Senior Manager. The Senior Manager is responsible for setting and implementing policies, expectations, and priorities to ensure that the functions being performed

by the Lead Laboratory are in accordance with the Lead Laboratory QA program. Supporting the Senior Manager is an organization that is responsible for performing the necessary scientific and technical work. The Lead Laboratory is supported by other organizations (e.g., other national laboratories subcontractors, Federal Agencies, and universities). Specific Lead Laboratory responsibilities are identified in the agreement between the OCRWM and the Lead Laboratory.

C. Principal Contractors QA Function

1. The M&O QA Manager reports directly to the M&O General Manager. The Lead Laboratory QA Manager reports directly to the Lead Laboratory Senior Manager.

2. Duties, responsibilities, and qualifications of the principal contractor' QA Manager as they pertain to the principal contractor', are the same as those of the Director, OQA, as delineated in Subsection 1.3.1B, with the following specific differences:

   a. Ensuring that the principal contractors' QA program is implemented consistent with the schedule for accomplishing the activities.

   b. Developing and maintaining the principal contractors' QA program document that implements the QARD.

   c. Reviewing and documenting concurrence (as specified in applicable procedures or procurement documents) of quality-related procedures.

   d. Verifying the adequacy and implementation (i.e., compliance and effectiveness) of the principal contractors' QA program and reporting the results to OCRWM and principal contractors' senior management. Verification methods include document reviews, audits, surveillances, and inspections, as appropriate.

   e. Performing the quality control related activities (e.g., inspection and nondestructive examination). (M&O only)

1.3.4 Waste Custodians (Spent Nuclear Fuel and High-Level Waste Form Producers)

OCRWM works to agreements that describe the interface with waste custodians (e.g., EM sites and the NNPP). These agreements shall identify scope, specify appropriate quality and technical requirements, and describe responsibilities and interfaces that apply to these entities. The measures taken to ensure that information supplied by waste custodians is suitable for use in supporting the license, and that waste forms are suitable for acceptance, are described in Appendix A, Waste Custodian Interface.

FIGURE 1

OCRWM ORGANIZATION

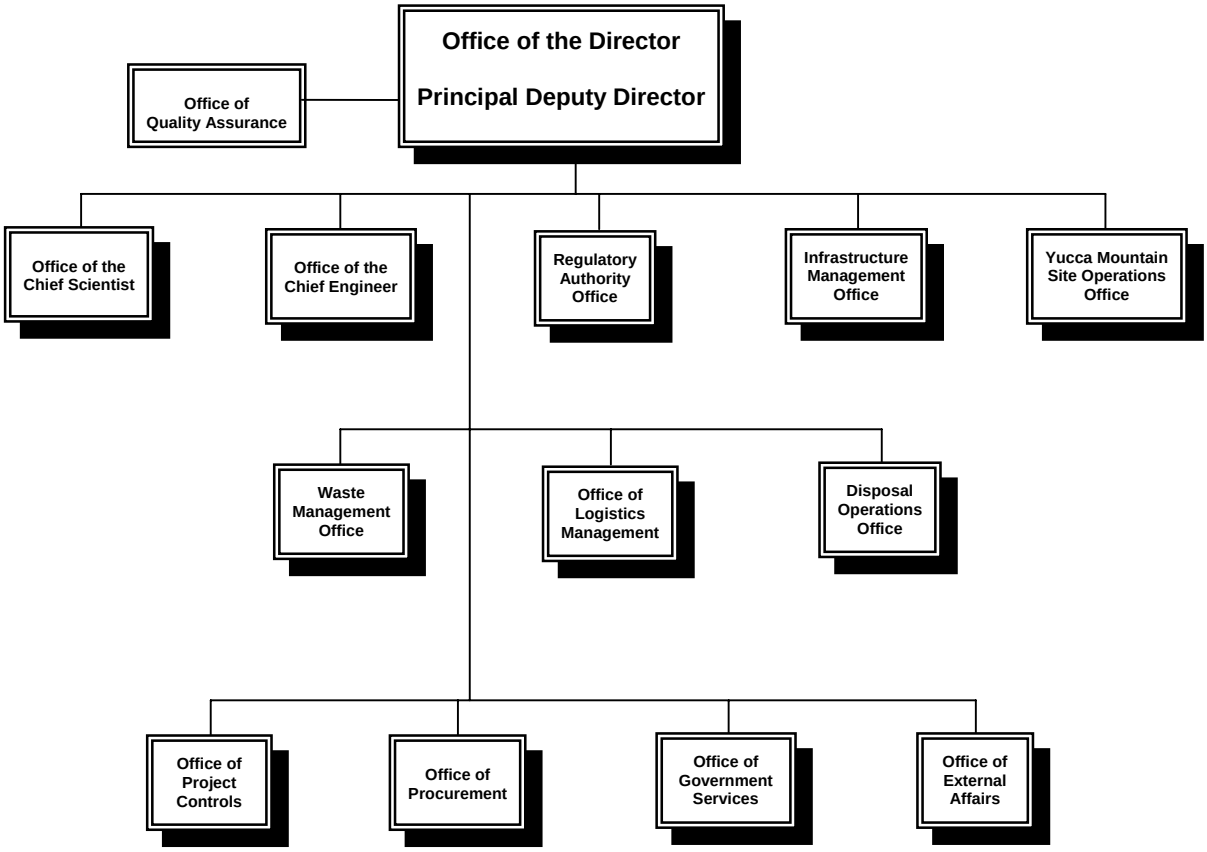
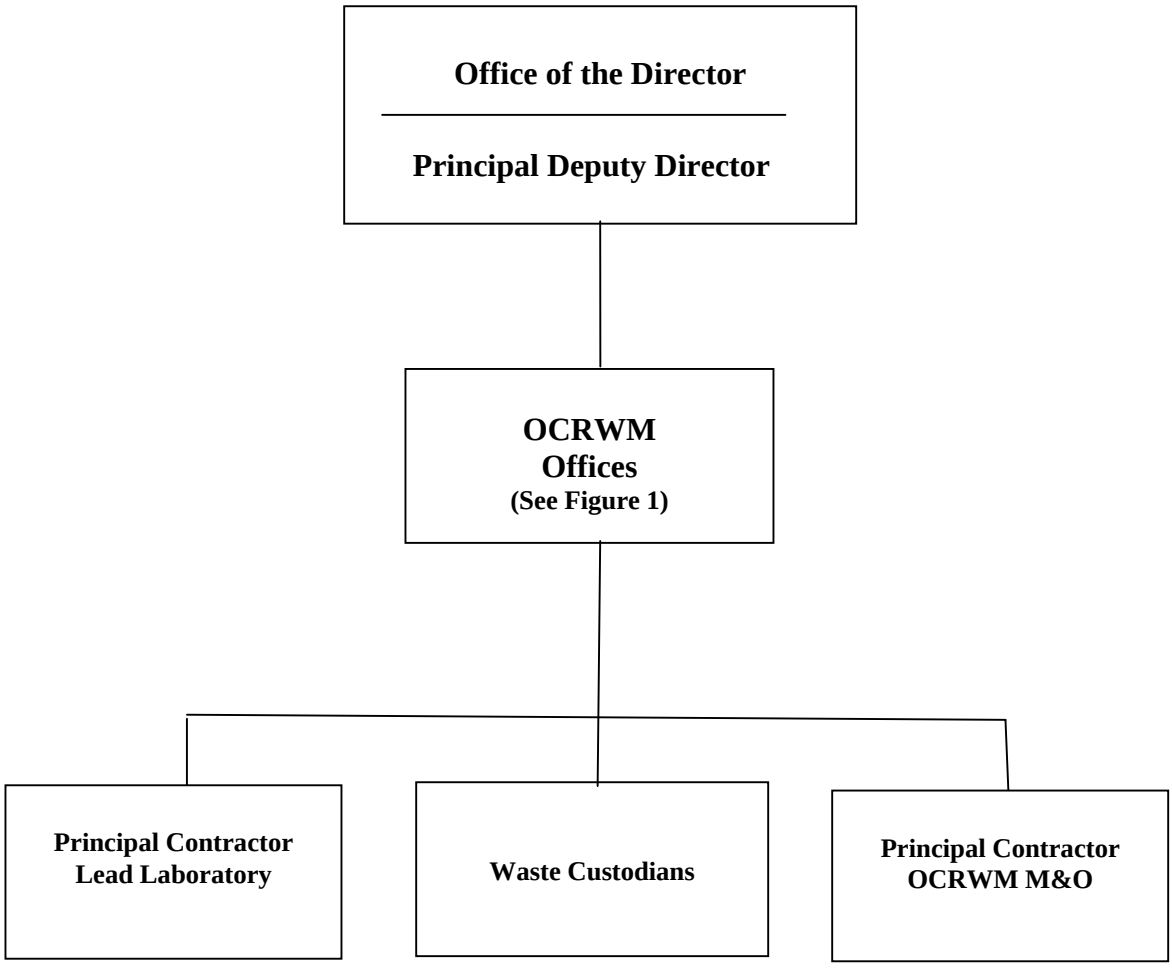


FIGURE 2

OCRWM EXTERNAL INTERFACES



2.0 QUALITY ASSURANCE PROGRAM

2.1 GENERAL

This section establishes the applicability of the QARD and the requirements for planning, implementing, and maintaining the OCRWM QA program. This section also establishes requirements for special topics related to the OCRWM QA program. The OCRWM QA program provides controls for activities affecting the quality of the SSCs within the scope of the OCRWM Program to an extent consistent with their importance to safety. The OCRWM QA program establishes requirements to ensure that work meeting the criteria described in Subsections 2.2.2 and 2.2.3 is performed under suitably controlled conditions, including the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for a given activity have been satisfied.

2.2 REQUIREMENTS

2.2.1 Quality Assurance Program Documents

A. The Director, OCRWM, shall issue a policy statement directing mandatory compliance with the QARD. The QA program description document of principal contractors shall have a similar requirement.

B. The OCRWM shall establish implementing documents to perform work that translates the QARD requirements into work processes. These implementing documents shall be controlled. The QA program description document of OCRWM contractors shall have a similar requirement. The following requirements apply to implementing documents:

1. A structured system of implementing documents shall provide for top-down implementation of upper-tier requirement documents and changes thereto.

2. The system shall accommodate the size and location(s) of the organization, the organizational structure, and the nature of the work such that management processes will be carried out efficiently and effectively.

3. The system shall provide positive control over internal and external organizational interfaces.

C. The OCRWM and principal contractors shall maintain a matrix or other similar cross-reference, consistent with their scope of work, which provides the relationship between the criteria of 10 CFR 63.142 to implementing documents.

2.2.2 Quality Assurance Program Applicability and Related Activities

The OCRWM QA program shall be applied to:

A. All SSCs important to safety or waste isolation

B. Design and characterization of barriers important to waste isolation

C. Related activities that are important to waste isolation and are important to safety functions of those SSCs include site characterization; acquisition, control, and analysis of samples and data; tests and experiments; scientific studies; performance of the preclosure safety analysis, total system performance assessment, and qualification of their inputs; facility and equipment design and construction (i.e., designing, purchasing, fabricating, handling, packaging, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, maintaining, repairing, and modifying); and performance confirmation.

2.2.3 Classifying Structures, Systems, and Components

The SSCs important to safety or waste isolation, barriers important to waste isolation, and consumables important to safety or waste isolation shall be classified based upon the importance to safety and/or importance to waste isolation. The classification of the SSCs important to safety or waste isolation, barriers important to waste isolation, and consumables important to safety or waste isolation shall be documented on a "Q-List."

2.2.4 Planning Work

Planning establishes the systematic, sequential progression of actions to meet the defined requirements.

A. Planning activities shall be performed and documented prior to the start of work.

B. Planning shall ensure that work is accomplished under suitably controlled conditions, which includes the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.

C. Planning shall provide for any special controls, processes, test equipment, tools, and skills needed to attain the required quality/verification of quality and the need for verification of quality by inspection and test.

2.2.5 Surveillances

Surveillances shall be:

A. Scheduled in a manner to provide coverage, consistency, and coordination of ongoing work, at a frequency commensurate with the status and importance of work

B. Performed by personnel who are knowledgeable about, and not directly responsible for, the work under surveillance

C. Documented in a report to appropriate management.

2.2.6 Management Assessments

The Director, OCRWM, shall perform or direct the performance of management assessments of the OCRWM organizations supporting the OCRWM Program and principal contractors. Management assessments shall:

A. Be performed by personnel outside the QA organization.

B. Be planned and documented, and performed annually.

C. Evaluate:

1. The adequacy of resources and personnel provided to achieve and ensure quality

2. The scope, status, and adequacy of the OCRWM QA program

3. The effectiveness of the OCRWM QA program

4. The programmatic compliance to the OCRWM QA program.

D. Identify and track corrective action.

2.2.7 Readiness Reviews

The need for readiness reviews shall be identified by the OCRWM or OCRWM contractor's management for major scheduled or planned work to ensure OCRWM Program objectives are met. Where needed, readiness reviews shall be conducted for the planned scope of work to ensure that objective evidence exists demonstrating that:

A. Work prerequisites have been satisfied.

B. Personnel have been suitably trained and qualified.

C. Appropriate implementing documents and management controls are available and approved.

2.2.8 Peer Reviews

Peer reviews shall be conducted in accordance with the requirements and recommendations of NUREG-1297, February 1988, as delineated in Table 1, Item D.

2.2.9 Expert Elicitation

Expert elicitation shall be conducted in accordance with requirements and recommendations of NUREG-1563, November 1996, as delineated in Table 1, Item F.

2.2.10 Quality Assurance Program Management Review

Management shall regularly review the scope, status, adequacy, and compliance aspects of the QA program they are executing and its compliance with 10 CFR 63, Subpart G, to assure its effective implementation. These reviews shall include frequent review of QA program status through reports, meetings, audits, surveillance, and observations. Appropriate management shall receive, as a minimum, audit reports, surveillance reports, trend reports, and management assessment reports.

2.2.11 Personnel Indoctrination, Training, Qualification, and Certification

Personnel indoctrination, training, and qualification processes shall be implemented in a manner that ensures the appropriate indoctrination, training, and qualification have been provided prior to performing activities that are important to safety or important to waste isolation. Personnel performing these activities are indoctrinated, trained, qualified, and certified as follows:

A. Personnel shall be indoctrinated and trained as follows:

1. Determine required indoctrination and training.

2. Document formal training including the objective, content of the training, attendees, and date of attendance.

3. Ensure personnel are indoctrinated and trained, as needed, to achieve initial proficiency; maintain proficiency; and to adapt to changes in technology, methods, or job responsibilities.

4. Personnel that require certification are given proficiency tests. Acceptance criteria are developed to determine whether individuals are properly trained and qualified.

5. Evaluate and assess the need for additional indoctrination and training as assignments, positions, or implementing documents change.

6. Ensure indoctrination and training are completed prior to performing the work.

7. Ensure that personnel are indoctrinated in the following topics as they relate to a particular function:

    a. General criteria, including the QARD, applicable codes, regulations, and standards

    b. QA practices, concepts, and requirements

    c. Applicable implementing documents

    d. Job responsibilities and authority.

B. Personnel performing inspections or tests shall be trained, qualified, and certified in accordance with the following requirements:

1. Regulatory Guide 1.28, Revision 3, Position C.1

2. ANSI/ASME NQA-1-1983 Edition

    a. Basic Requirement 2, Quality Assurance Program

    b. Supplementary Requirement 2S-1, Supplementary Requirements for the Qualification of Inspection and Test Personnel

    c. Appendix 2A-1, Nonmandatory Guidance on the Qualification of Inspection and Test Personnel.

C. Personnel performing as auditors and technical specialists shall be trained and qualified, and lead auditors shall be trained, qualified, and certified in accordance with the requirements of ANSI/ASME NQA-1-1983 with ANSI/ASME NQA-1A-1983 addenda, as follows:

1. Supplementary Requirement 2S-3, Supplementary Requirements for the Quality Assurance Program Audit Personnel

2. Appendix 2A-3, Nonmandatory Guidance on the Education and Experience of Lead Auditors.

D. Personnel who perform nondestructive examinations shall be trained, qualified, and certified in accordance with the American Society for Nondestructive Testing, *Recommended Practice No. SNT-TC-1A*, June 1980 Edition. In lieu of the three-year recertification interval specified in the *Recommended Practice No.*

SNT-TC-1A, June 1980 Edition, Level III nondestructive examination personnel may be recertified on a five-year interval.

E. When required by codes, standards, and specifications, personnel who perform inspections shall be certified in accordance with the pertinent codes, standards, and specifications, (i.e., American Welding Society [Certified Welding Inspector], National Electric Code [Certified Electrical Inspector], American Concrete Institute [Concrete Construction Inspector, Concrete Transportation Inspector], etc.). Validity of these certifications shall be verified prior to performing inspections.

F. Qualifications for the Director, OQA, M&O QA Manager, and Lead Laboratory QA Manager include:

1. Management experience through assignments to responsible positions

2. In-depth knowledge of QA regulations, policies, practices, and standards

3. Appropriate experience working in QA or related activity in nuclear-related design, construction, or operation or a similar technically based industry

4. Meeting or exceeding the qualification requirements for the Quality Assurance position specified in ANSI/ANS-3.1-1993, Paragraph 4.3.7, as modified by Regulatory Guide 1.8, Revision 3 (5/2000), Regulatory Position C.2.1.1.

3.0 DESIGN CONTROL

3.1 GENERAL

A. This section provides requirements to ensure that designs are defined, controlled, and verified. The scope of the design control program includes design activities associated with the preparation and review of design documents, including the correct translation of applicable regulatory requirements, design bases, and site characteristics into design, procurement, and procedural documents (such as drawings, calculations, specifications, plans, and procedures). Included in the scope are activities such as field design engineering; physics (including criticality physics); seismic, stress, thermal, hydraulic, and preclosure and postclosure analyses; radiation shielding; compatibility of materials; delineation of acceptance criteria for inspections and tests; Safety Analysis Report event sequence analyses and associated computer software; features to facilitate decontamination; suitability; and accessibility for in-service inspection, maintenance, repair, and quality standards.

B. Design control measures shall be established and are applied to (i) the design of items that are important to safety; (ii) engineered and natural barriers that are important to waste isolation; (iii) the description of the geologic setting and the plans for data collection and analysis activities that will generate information pertinent to the repository design and that will be relied on in site characterization, licensing, and performance confirmation; (iv) computer software used in such activities; and (v) development of as-built drawings and related documentation in a timely manner. These design measures shall apply to the design inputs, outputs, and performance confirmation activities.

C. Computer software used in all design activities shall be developed or procured, qualified, and used in accordance with Supplement I, Software.

3.2 REQUIREMENTS

3.2.1 Design Input Control

Applicable design inputs such as design bases, conceptual design reports, performance requirements (including those resulting from postclosure analyses), regulatory requirements, codes, and standards shall be controlled by those responsible for the design according to the following requirements:

A. Design inputs shall be identified and documented, and their selection reviewed and approved, by those responsible for the design.

B. Design inputs shall be specified and approved on a timely basis and to the level of detail necessary to permit the design work to be carried out in a correct manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.

C. Data from scientific investigation activities used as design input shall be qualified in accordance with Supplement III, Scientific Investigation, prior to use in the design product.

D. Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.

E. Design inputs based on assumptions that require confirmation shall be identified and controlled as the design proceeds.

3.2.2 Design Process

The design process shall be controlled according to the following requirements:

A. Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit (i) the design process to be carried out in a correct manner and (ii) verification that the design meets requirements.

B. Design documents shall be adequate to support design, fabrication, construction, and operation. The documentation shall include not only the final design documents, such as drawings, specifications, and their revisions, but also documentation that identifies the important steps, including sources of design inputs supporting the final design.

C. Appropriate technical and QA standards shall be identified and documented, and their selection reviewed and approved.

D. Changes or deviations from specified quality assurance and technical standards, including the reasons for the change or deviation, shall be identified, evaluated, approved, documented, and controlled.

E. Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are important to waste isolation or important to safety functions of SSCs.

F. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

G. The final design (approved design documents and approved changes thereto) shall:

1. Be relatable to the design input by documentation in sufficient detail to permit design verification

2. Identify assemblies and/or components that are part of the item being designed.

H. For commercial grade items, the critical characteristics to be verified and the acceptance criteria for those characteristics shall be documented. If a commercial grade assembly or component, prior to installation, is modified or selected by special inspection and/or testing to meet requirements that are more restrictive than the supplier's published product description, then the item shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference.

I. The dimensional accuracy and completeness of design drawings and specifications shall be checked and documented.

J. Design drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.

K. Design documents shall be reviewed by individuals or groups within the QA organization that do not have direct responsibility for performing the work being verified, or by individuals or groups other than the one who generated the document and trained and qualified in QA practices and concepts. Reviews shall be performed to assure that the documents are prepared, reviewed, and approved in accordance with implementing procedures and contain the necessary QA requirements, such as inspection and test requirements, acceptance requirements, and the extent to which inspection and test results are required to be documented. Training and qualification of non-QA organization individuals shall be in accordance with Subsection 2.2.11.

L. The distribution and use of design documents shall be controlled in accordance with Section 6.0.

3.2.3 Design Analyses

A. Design analyses shall be planned, controlled, and documented.

B. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval.

C. Design analysis documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify their adequacy without recourse to the originator.

D. Calculations shall be identifiable by subject (including SSC to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are traceable and retrievable.

E. Documentation of design analyses shall include:

1. Definition of the objective of the analyses

2. Definition of design inputs and their sources

3. Results of literature searches or other applicable background data

4. Identification of assumptions and indication of those that must be verified as the design proceeds

5. Identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) that support application of the computer program to the specific physical problem.

6. Computer programs may be utilized for design analysis without individual verification of the program for each application, provided:

   a. The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.

   b. The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

7. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes to Paragraph 3.2.3E.6.a and 3.2.3E.6.b.

8. Identification of the originator, reviewer, and approver.

3.2.4 Design Verification

A. Design verification shall be performed to determine the adequacy of design by using one or a combination of the following methods:

   1. Design review (see Paragraph 3.2.5A)
   2. Alternate or simplified calculations (see Paragraph 3.2.5B)
   3. Qualification testing (see Paragraph 3.2.5C).

B. The extent of design verification required is a function of the importance to safety or waste isolation of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs.

C. Guidelines or criteria shall be established and described for determining the method of design verification. The particular design verification method used shall be identified and documented.

D. Procedural controls shall provide criteria for determining when design documents that reflect the commitments of the Safety Analysis Report receive formal design verification by interdisciplinary or multi-organizational teams or by a single individual (a signature and date are acceptable documentation). Design documents subject to procedural controls include, but are not limited to, specifications, calculations, associated computer software supporting a safety or waste isolation function, system descriptions, parts of the Safety Analysis Report when used as a design document, and drawings, including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

E. The results of design verification shall be documented, including the identification of the verifier.

F. Responsibilities of the verifier, areas and features to be verified, pertinent considerations to be verified, and the extent of documentation shall be identified in procedures.

G. Design verification shall be performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. In exceptional circumstances, this verification may be performed by the originator's immediate supervisor, provided:

1. The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design.

2. The supervisor is the only individual in the organization competent to perform the verification.

3. The verification is not a cursory review.

4. The determination to use the supervisor is documented and approved in advance by the supervisor's management.

5. QA audits are conducted to evaluate the frequency and effectiveness of the use of supervisors as design verifiers.

H. Design verification shall be performed at appropriate times and in a timely manner during the design process.

1. Design verification shall be performed before release for procurement, manufacture, or construction or the release to another organization for use in other design work. In cases where this timing cannot be satisfied, the design verification may be deferred, providing that a justification for this

action is documented and the unverified portion of the design output document and all design output documents based on the unverified portion are appropriately identified and controlled.

2. Construction site activities associated with a design or design change shall not proceed without verification past the point where installation would become irreversible (i.e., require extensive demolition and rework).

3. In all cases, design verification shall be completed before waste package placement in the repository or before relying on the SSC to perform its safety function.

I. Where the design has been subjected to a previous verification process in accordance with the QARD, the verification process need not be duplicated for identical designs.

J. Use of previously proven designs shall be controlled in accordance with the following requirements:

1. The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application.

2. Known problems affecting standard or previously proven designs and their effects on other features shall be considered.

3. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

K. Changes in previously verified designs shall require reverification. Such verification shall include the evaluation of the effects of the changes on the overall previously verified design and on any design analyses upon which the design is based. Design changes shall be controlled in accordance with Subsection 3.2.6.

3.2.5 Design Verification Methods

A. Design Review

Design reviews shall be controlled and performed to ensure:

1. The design inputs were correctly selected and incorporated.

2. The assumptions necessary to perform the design were adequately described, reasonable, and where applicable, identified as requiring confirmation as the design proceeds.

3. Appropriate design methods, and computer programs where applicable, were used.

4. Design inputs were correctly incorporated into the design.

5. The design outputs are reasonable compared to design inputs.

6. The necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing documents.

B. Alternate or Simplified Calculations

These are calculations or analyses that are made with alternate methods to verify correctness of the original calculation or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall be reviewed.

C. Qualification Testing

1. Where design adequacy is to be verified by qualification tests, the tests shall be identified.

2. Prototype, component, or feature testing shall be performed as early as possible before the installation would become irreversible.

3. The test configuration shall be defined and documented.

4. Testing shall demonstrate the adequacy of system, structure, or component performance under conditions that simulate the full range, including the most adverse anticipated design conditions as determined by analysis. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions.

5. If the tests verify only specific design features, the other features of the design shall be verified by other means.

6. Test results shall be documented and evaluated by the responsible design organization to ensure that test requirements have been met.

7. If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to ensure satisfactory performance.

8. When tests are being performed on models or mockups, scaling laws shall be established, verified, and approved.

9. The results of model test work shall be subject to error analysis, where applicable, before using the results in the final design.

3.2.6 Design Change Control

Design changes, including field changes, shall be controlled in accordance with the following requirements:

A. Changes to final designs, field changes, and nonconforming items dispositioned "use-as-is" or "repair" shall be justified and shall be subject to design control measures commensurate with those applied to the original design.

B. Changes shall be approved by the same affected groups or organizations that approved the original design documents.

   1. If an organization that originally was responsible for approving a particular design document is no longer responsible, a new responsible organization shall be designated by the OCRWM.

   2. The designated approving organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

C. The design process and design verification methods and implementing documents shall be reviewed and modified, as necessary, when a significant design change is necessary because of an incorrect design.

D. Errors and deficiencies in approved design documents, including design methods (i.e., computer software supporting a safety or waste isolation function), that could adversely affect SSCs important to safety or waste isolation shall be documented and action taken to ensure all errors and deficiencies are corrected.

E. Deviations from specified quality standards shall be identified and formally documented. Procedures shall be established to ensure control of these deviations.

F. Measures shall be provided to ensure personnel are notified of design changes/modifications that may affect the performance of their duties.

G. Prior to the issuance of a design change initiated after the construction authorization, the design changes shall be evaluated pursuant to applicable regulatory requirements.

3.2.7 Design Interface Control

A. Design interfaces shall be identified and controlled.

B. Design efforts shall be coordinated among participating design organizations and across technical disciplines. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating design organizations and technical disciplines for the review, approval, release, distribution, and revision of documents involving design interfaces to ensure that SSCs are compatible geometrically, functionally, and with processes and environment.

C. Design information transmitted across interfaces shall be documented and controlled.

D. The status of the design information or document provided shall be identified in transmittals.

E. When it is necessary to initially transmit design information orally or by other informal means, the design information shall be promptly confirmed with formal documentation initiated in accordance with the initiating organization's approved implementing document.

3.2.8 Sampling Plans

The basis, including any supporting analyses for the use of sampling plans for items, barriers, and related activities, shall be documented. The following apply to the use of sampling plans:

A. Sampling plans shall use a criterion that provides 95 percent confidence that there are only 5 percent defective items in a lot (95/5).

B. Lots sampled shall be essentially homogeneous.

C. Sample plans shall be based on recognized standard practices.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 GENERAL

A. This section establishes requirements to ensure that procurement documents, and any changes thereto, contain appropriate technical and QA requirements.

B. When an Interagency Agreement or other document serves as a procurement document between the OCRWM and other federal agencies, the requirements of this section shall apply.

C. The requirements of this section that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

4.2 REQUIREMENTS

4.2.1 Procurement Document Preparation

Procurement documents shall include the following provisions to assure quality, as applicable to the item (including spare parts and replacements) or service being procured:

A. A statement of the scope of work to be performed.

B. Technical requirements, including:

1. Design bases shall be identified or referenced.

2. Specific documents (i.e., drawings, specifications, codes, standards, regulations, procedures, or instructions), including revisions thereto, that describe the technical requirements of the items or services to be furnished shall be specified. The revision level or change status of these documents shall also be identified.

3. Tests, inspections, and acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier shall be specified.

C. QA program requirements, including:

1. A requirement for the supplier to provide, upon request, a documented QA program that implements applicable QA requirements prior to the initiation of work. A principal contractor's QA program description document shall comply with the QARD. A supplier's QA program description documents shall comply with the purchaser's QA program description document. The extent of the QA program shall depend on the scope, nature, type and use, or complexity of the item or service being procured.

2. A requirement for supplier to incorporate the appropriate QA requirements into any supplier procurement document issued to a subtier supplier.

3. When deemed appropriate, a requirement for the purchaser to permit some or all supplier work to be performed under the OCRWM QA program or the purchaser's QA program. In these cases, procurement documents shall specify that the OCRWM's or the purchaser's implementing documents are applicable to the supplier and that the purchaser shall provide these applicable documents to the supplier.

4. As an alternative to requiring a documented QA program for suppliers of analytical services (measurement of properties or other characterization of samples) supporting scientific investigations, these procurements may be controlled in accordance with Subsection 7.2.12B.

5. When required data cannot be obtained from an external source through a procurement process that involves the imposition of applicable QA program requirements, the data may be obtained through a non-Q procurement action in accordance with Subsection 7.2.12C.

D. Provisions for right of access to supplier's facilities shall be granted at each tier of procurement for the purpose of inspection, verification, audit, or surveillance by the purchaser or other designee authorized by the purchaser. Procurement documents issued by OCRWM contractors shall also include a provision to provide right of access to the OQA for the purpose of inspection, verification, audit, or surveillance by the OQA.

E. Provisions for establishing hold points beyond which work cannot proceed without purchaser authorization.

F. Identification of the schedule for submittal of documents to the purchaser for information, review, acceptance, and retention.

G. Purchaser requirements for the supplier to report nonconformances dispositioned "use-as-is" or "repair" to the purchaser for approval of the disposition.

H. Identification of any spare and replacement parts or assemblies and the appropriate technical and QA information required for ordering. Spare parts shall be subject to QA program controls, codes and standards, and technical requirements equal to or greater than the original requirements, or as required to preclude repetition of defects.

I. Instructions relative to the performance of special processes.

J. A requirement for suppliers to establish controls to mitigate the procurement and installation of counterfeit or fraudulent items.

K. Provisions for identifying that the procurement is subject to the provisions of 10 CFR 21.

4.2.2 Procurement Document Review and Approval

A. Procurement document reviews shall be performed and documented prior to issuance of the procurement documents.

B. A review of the procurement documents and any changes thereto shall be made to verify that documents include appropriate provisions to ensure that items or services will meet the governing requirements.

C. Reviews shall ensure that all applicable requirements delineated in Subsection 4.2.1 are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed, and approved in accordance with the requirements of this section.

D. Reviews shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and scope of the procurement.

E. Procurement documents shall be reviewed by individuals or groups within the QA organization that do not have direct responsibility for performing the work being verified, or by individuals or groups other than the one who generated the document that are trained and qualified in QA practices and concepts and concur with these documents with respect to the QA-related aspects. The training and qualification of non-QA organization individuals shall be in accordance with Subsection 2.2.11.

F. Procurement documents shall be approved.

4.2.3 Procurement Document Change

A. Changes shall be subject to the same degree of control as used in the preparation of the original documents.

B. Changes made as a result of proposal/bid evaluations or pre-contract negotiations shall be incorporated into the procurement documents. The evaluation of these changes and the resulting impact shall be completed before the contract is awarded. The evaluation shall consider:

1. Appropriate requirements as specified in this section

2. Additional or modified design criteria

3. Analysis of exceptions or changes requested or specified by suppliers and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished.

4.2.4 Procurement Document Control

The distribution and use of procurement documents and changes thereto shall be controlled in accordance with Section 6.0.

5.0 PROCEDURES, INSTRUCTIONS, AND DRAWINGS

5.1 GENERAL

This section establishes the requirements to ensure that work is prescribed by, and performed in accordance with, approved procedures, instructions, and drawings, (i.e., implementing documents).

5.2 REQUIREMENTS

A. Work shall be prescribed by controlled implementing documents of a type appropriate to the circumstance and shall be accomplished in accordance with these implementing documents.

B. Work shall be suspended if it cannot be accomplished as described in controlled implementing documents.

C. OCRWM contractors may work to OCRWM's or a principal contractor's implementing documents when stipulated in procurement documents, in accordance with Section 4.0.

D. Suppliers to a principal contractor may work to OCRWM's or the principal contractor's implementing documents, if permitted by the principal contractor's QA program description document and if stipulated in procurement documents.

5.2.1 Types of Implementing Documents

The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. Design drawings, including as-built drawings, are developed and controlled in accordance with the requirements of Section 3.0.

5.2.2 Content of Implementing Documents

A Implementing documents shall be consistent with requirements delineated in the QA program description document applicable to the implementing organization and shall include the following information, as appropriate to the work to be performed:

1. Responsibilities and organizational interfaces of the organizations affected by the document

2. A sequential description of the work to be performed, if necessary to satisfactorily complete the work, including controls for altering the sequence

3. Quantitative and/or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished and that prescribed results have been satisfactorily attained

4. Methods for documenting that the work was performed as specified

5. Identification of the QA records generated by the implementing document.

B. The organization responsible for the implementing document shall determine the appropriate level of detail.

5.2.3 Review, Approval, and Control of Implementing Documents

Implementing documents shall be reviewed, approved, and controlled in accordance with Section 6.0.

6.0 DOCUMENT CONTROL

6.1 GENERAL

This section establishes requirements to ensure documents that specify technical or quality requirements or prescribe activities affecting quality, including changes thereto, are reviewed for adequacy, approved for release, distributed for use at the location where the work is being performed, and used at the work location.

6.2 REQUIREMENTS

6.2.1 Types of Documents

A. Implementing documents and documents that specify technical requirements or quality requirements or prescribe activities affecting quality shall be controlled in accordance with this section.

B. Controlled documents shall include, but not be limited to design documents (including as-builts), procurement documents, procedures, instructions, QA program description and requirements documents, and Safety Analysis Reports, including changes thereto.

6.2.2 Preparing Documents

The responsibility for preparing documents shall be assigned to the appropriate organization.

6.2.3 Reviewing Documents

Implementing documents and documents that specify technical or quality assurance requirements or prescribe activities that are governed by the QARD, including changes thereto, shall be reviewed prior to the start of work with respect to the following requirements and to any additional requirements specified by the applicable section of the QARD.

A. Review criteria shall be established before performing the review. The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements.

B. The review shall be performed by individuals other than the preparer.

C. Reviewers shall be technically competent for the subject area of the document being reviewed.

D. Reviewers shall have access to pertinent background data or information upon which to base their acceptance.

E. Reviewers shall document acceptance.

F. Reviewers include:

1. Organizations or technical disciplines affected by the document as determined by the manager responsible for the implementing document.

2. Individuals or groups within the QA organization that do not have direct responsibility for performing the work being verified, or individuals or groups other than the one who generated the document that are trained and qualified in QA practices and concepts and concur with these documents with respect to the QA-related aspects. The training and qualification of non-QA organization individuals shall be in accordance with Subsection 2.2.11.

3. The OCRWM, for principal contractors' procedure(s) that directs the development and maintenance of their quality-affecting procedures. Review shall be performed and acceptance documented prior to initiation of the activity governed by the procedure.

G. Comments resulting from the review shall be documented and resolved to the satisfaction of the organization responsible for the document before approving the document.

6.2.4 Approving Documents

The organizational position responsible for approving the document for release shall be identified.

6.2.5 Distribution and Use of Documents

A. A system shall be established to identify the current status of each document that is required to be controlled in accordance with this section. This system shall be made accessible to document users.

B. The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work.

C. Effective dates shall be established for approved implementing documents.

D. The latest version (revision or change) of documents either in hardcopy or electronic media shall be available for use prior to the start of work at the location where the activity is performed. Documents shall be adhered to in the performance of work.

6.2.6 Changes to Documents

A. Changes to documents shall be reviewed in accordance with the requirements of Subsection 6.2.3, prior to approval for release.

B. Changes shall be approved for release in a timely manner by the designated organizational position responsible for the document.

C. Implementing documents shall define the method used to incorporate changes. If the defined method is other than reissue of the entire revised controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document.

D. Implementing documents shall require that a history of changes to QA program documents, including the reasons for the changes, be documented and maintained. This document history shall be reviewed each time additional changes to the document are proposed.

E. Changes to documents, other than editorial corrections as delineated in Subsection 6.2.8, shall be reviewed and approved by the same organizations that performed the original review and approval unless OCRWM designates another responsible organization. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.

6.2.7 Expedited Changes

If an activity cannot be performed as prescribed in a document and the change process would cause unreasonable delays, an expedited change may be made at the work location by responsible management.

A. After the expedited change has been authorized, the changes shall be processed through the normal change process. This processing shall occur in a timely manner consistent with the type and nature of the document being changed.

B. Implementing documents shall describe the process to control expedited changes according to the following requirements.

1. The level of management with the authority to make expedited changes shall be identified.

2. The time limits for processing expedited changes through the normal change process shall be specified.

3. An evaluation of the work shall be performed, if the normal review process results in a change that is different from the expedited change.

6.2.8 Editorial Corrections

Inconsequential editorial corrections may be made to documents without being subject to review requirements, but such corrections shall be distributed as a revision or change to the document.

A. The following items are considered editorial corrections:

1. Correcting grammar or spelling.

2. Renumbering sections or attachments that do not affect the chronological sequence of work.

3. Changing the title or number of the document or the title or number of documents referenced in the procedure.

4. Updating organizational titles.

B. A change in an organizational title accompanied by a change in responsibilities is not considered an editorial correction.

C. The organizational position responsible for approving the document for release shall approve editorial corrections.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 GENERAL

A. This section establishes requirements for planning and executing quality affecting procurements to ensure that purchased items and services meet specified requirements. This section does not apply to the procurement of direct support contractor services or other non-quality affecting procurements. The supplier selection and bid/proposal evaluation requirements of this section do not apply to situations where the OCRWM obtains the services of other federal agencies through an Interagency Agreement or other such document. When an Interagency Agreement or other such document serves as a procurement document between the OCRWM and other federal agencies, the technical and quality requirements, responsibilities, and interfaces specified in these documents shall be verified to be satisfactorily incorporated into the applicable federal agency's QA program description document prior to starting work subject to the QARD.

B. The requirements of this section that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

7.2 REQUIREMENTS

7.2.1 Procurement Planning

Procurements shall be planned and documented to ensure a systematic approach to the procurement process. Procurement planning shall:

A. Identify procurement methods and organizational responsibilities, including interfaces between design, procurement, and QA organizations.

B. Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.

C. Prior to the initiation of each individual activity identified in Paragraph 7.2.1D, identify and document the sequence of actions and milestones, indicating the completion of these activities and the preparation of applicable procedures.

D. Provide for the integration of the following activities:

1. Procurement document preparation, review, and change control according to the requirements of Section 4.0

2. Selection of procurement sources

3. Proposal/bid evaluation and award

4. Evaluation of OCRWM contractor/supplier performance

5. Verifications, including any hold and witness point notifications

6. Control of nonconformances

7. Corrective action

8. Acceptance of the item or service

9. Identification of QA records.

E. Be accomplished as early as practicable, and no later than the start of those procurement activities that are required to be controlled, to ensure interface compatibility and a uniform approach to the procurement process.

F. Be performed relative to the level of importance, complexity, and quantity of the item or service being procured and the supplier's quality performance.

G. Include participation of representatives from the technical organizations and the QA organization.

7.2.2 Source Evaluation and Selection

A. Supplier selection shall be based on an evaluation, performed by or for the purchaser before the contract is awarded, to determine the supplier's capability to provide items or services in accordance with procurement document requirements.

B. The organizational responsibilities of the purchaser for source evaluation and selection shall be identified, including provisions for input from the QA organization.

C. The purchaser's measures for evaluating and selecting procurement sources shall be documented and shall include one or more of the following elements:

1. Evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use. This evaluation shall reflect current capability.

2. Evaluation of the supplier's current QA records, supported by documented qualitative and quantitative information that can be objectively evaluated.

3. Evaluation of the supplier's technical and quality capability are determined by a direct evaluation of supplier's facilities and personnel, and the implementation of supplier's QA program.

D. The results of procurement source evaluation and selection shall be documented.

7.2.3 Proposal/Bid Evaluation

A. The proposal/bid evaluation process shall include a determination of the extent of conformance to the procurement document requirements. This evaluation shall be performed by designated, technically qualified organizations, including the QA organization.

B. The evaluation shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured:

1. Technical considerations
2. QA program requirements
3. Supplier's personnel
4. Supplier's production capability
5. Supplier's past performance
6. Alternatives
7. Exceptions.

C. Before the contract is awarded, the purchaser shall resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.

D. Any deficiencies that would affect quality shall be corrected before starting quality affecting work.

E. Supplier's QA program description document shall be accepted by the purchaser prior to the start of work.

7.2.4 Supplier Performance Evaluation

A. The purchaser of items and services shall establish measures to interface with the supplier to verify performance. The measures shall include:

1. Establishing an understanding between the purchaser and supplier regarding the requirements and specifications identified in the procurement documents

2. Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements

3. Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements

4. Identifying and processing necessary change information

5. Establishing the method to be used to document information exchanges between purchaser and supplier

6. Establishing the extent of source surveillance and inspection.

B. Annual performance evaluations shall be performed on each supplier to determine the need to schedule additional audits. This evaluation shall be documented and based on:

1. Review of supplier furnished documents and records (i.e., certificates of conformance, the American Society of Mechanical Engineers [ASME] Certificate of Authorization, ASME Quality System Certificate, nonconformance notices, and corrective actions)

2. Results of previous source verifications, audits, management assessments, and receiving inspections, including results of audits from other sources (e.g., other customers, ASME, NRC)

3. Operating experience of identical or similar products furnished by the same supplier.

C. The extent of verifications, including planning, shall be a function of the relative importance, complexity, and quantity of items or services being procured and the supplier's quality performance.

D. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the supplier activities.

E. Verifications shall be conducted as early as practical and shall not relieve the supplier of their responsibility for the verification of quality achievement. Verifications shall include (i) the use of audits to evaluate the supplier's performance and (ii) evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's QA program. This documentation shall include, as appropriate, documentation of source surveillance and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions.

F. In order to determine the effectiveness of a supplier's QA program, the purchasers of items and services shall evaluate documentation related to that effectiveness, such as surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective action as they relate to the scope of a procurement.

7.2.5 Control of Supplier Generated Documents

A. Supplier generated documents shall be controlled, processed, and accepted in accordance with the requirements established in the procurement documents.

B. Measures shall be implemented to ensure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures shall provide for the acquisition, processing, and recorded

evaluation of technical, inspection, and test data compared against the acceptance criteria.

7.2.6 Acceptance of Items or Services

A. Suppliers shall verify that furnished items or services comply with the purchaser's procurement document requirements before offering the items or services for acceptance.

B. Suppliers shall provide the purchaser objective evidence that items or services conform to procurement documents. The documentation shall be available at the purchaser's facility before the item is installed or before the service is used.

C. Methods for accepting supplier furnished items or services shall ensure that items or services comply with the purchaser's procurement document requirements and include one or more of the following, as appropriate to the items or services being procured:

1. Evaluating the supplier's certificate of conformance (items and related services)

2. Performing one or a combination of source verification, receiving inspection, or post-installation test (items and related services)

3. Technical verification of data produced (services only)

4. Surveillance and/or audit of the activity (services only)

5. Review of objective evidence (i.e., certifications, stress reports, etc.) for conformance to the procurement document requirements (services only).

D. Purchaser shall accept items and services prior to installation or use.

7.2.7 Certificate of Conformance

When a certificate of conformance is used to accept an item or related service:

A. The certificate shall identify the purchased item or service to the specific procurement document.

B. The certificate shall identify the specific procurement document requirements met by the purchased item or service, such as codes, standards and other specifications. The procurement document requirements identified shall include any approved changes, waivers, or deviations applicable to the item or service.

C. The certificate shall identify any procurement document requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

D. The certificate shall be attested to by a person who is responsible for this QA function and whose responsibilities and position are described in the supplier's QA program.

E. The certification process, including the implementing documents to be followed in filling out a certificate and the administrative implementing documents for review and approval of the certificates, shall be described in the supplier's QA program description document.

F. Measures shall be identified to verify the validity of certificates and the effectiveness of the certification process (e.g., by audit of the supplier or by an independent inspection or test of the item). Verifications shall be conducted at intervals commensurate with the past quality performance of the supplier.

7.2.8 Source Verification

The purchaser may accept an item or service by monitoring, witnessing, or observing activities performed by the supplier. This method of acceptance is called source verification.

A. Verification of activities is planned and performed with QA organization participation in accordance with written procedures to ensure conformance to procurement requirements. Procedures applicable to the method of procurement provide for:

1. Specification of the characteristics or processes to be witnessed, inspected, or verified and the method of surveillance and the extent of documentation required.

2. Audits, surveillance, or inspections to verify the effectiveness of the supplier's QA program and quality control activities and to ensure that the supplier complies with quality assurance and technical requirements.

B. Source verification shall be implemented to inspect, monitor, witness, or observe activities consistent with the supplier's planned fabrication, inspections, examinations, or tests, and shipments of items at predetermined points and performed at intervals consistent with the importance and complexity of the item.

C. Documented evidence of acceptance of source verified items or services shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.

7.2.9 Receiving Inspection

When receiving inspection is used to accept an item:

A. The inspection shall consider the results of source verifications and audits and the demonstrated quality performance of the supplier.

B. The inspection shall be performed in accordance with inspection implementing documents.

C. The inspection shall verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.

D. The inspection shall be planned and executed according to the requirements of Section 10.0.

E. Receiving inspection shall be coordinated with a review for adequacy and completeness of any required documentation submittals.

7.2.10 Post-Installation Testing

A. When post-installation testing is used as a method of acceptance, the post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier.

B. The test shall be in accordance with the requirements of Section 11.0.

7.2.11 Control of OCRWM Contractor's/Supplier's Nonconformances

The purchaser and supplier shall establish and document the process for disposition of items and services that do not meet procurement document requirements according to the following requirements:

A. OCRWM contractors, other than principal contractors, shall evaluate nonconforming items according to the requirements of Section 15.0. Principal contractors shall evaluate nonconforming items according to the requirements of their QA program description document.

B. Suppliers/principal contractors shall submit a report of nonconformance to the purchaser, including recommended disposition for "use-as-is" or "repair," and technical justification. Reports of nonconformances related to procurement document requirements or documents approved by the purchaser shall be submitted to the purchaser for approval of the recommended disposition whenever one of the following conditions exists:

1. Technical or material requirements are violated.

2. A requirement in supplier documents, which have been approved by the purchaser, is violated.

3. The nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.

4. The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

C. The purchaser shall disposition the supplier's recommendation.

D. The purchaser shall verify implementation of the disposition.

E. The purchaser shall maintain records of supplier submitted nonconformances.

7.2.12 Commercial Grade Procurement

A. Commercial Grade Items

Where specific quality assurance controls appropriate for nuclear applications cannot be imposed in a practicable manner, commercial grade items may be substituted for basic components, subject to the following to provide the necessary assurance that the dedicated item will perform its intended safety or waste isolation function:

1. The item's critical characteristics shall be specified in approved design and procurement documents.

2. Verification of the item's critical characteristics shall be achieved by application of a dedication process to be performed by a specified dedicating entity.

3. Implementing processes shall be developed to be consistent with Electric Power Research Institute (EPRI) *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications* (NCIG-07), EPRI NP-5652 (6/88), as endorsed and modified by NRC Generic Letters 89-02, *Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products* (3/89) and 91-05, *Licensee Commercial-Grade Procurement and Dedication Programs* (4/91).

B. Commercial Grade Analytical Services

For analytical services in support of scientific investigation, the following requirements shall be an acceptable alternative to all other requirements of Section 7.0. The purchaser shall:

1. Prior to issuing the procurement document, develop a documented quality control sample plan that describes:

a. The number of quality control samples and approach to be used for submitting the samples (e.g., blind, duplicate, spike, etc.).

b. The preparation and analysis of quality control samples or the identification of the source of the preparation and analysis method. Standards used in the preparation of quality control samples shall be traceable to nationally recognized standards. If no nationally recognized standard exists, the basis for use shall be documented.

c. Acceptance criteria.

d. How the number of quality control samples, the approach, and the acceptance criteria provide confidence in the accuracy/precision of the data.

2. Ensure that quality control analytical results are received and evaluated against acceptance criteria, prior to use of data.

3. Ensure that data, quality control analytical results, the quality control sample plan, and evaluation documentation are submitted as QA records.

C. Commercial Grade Data

When required data cannot be obtained from any external source through a procurement process that involves the imposition of applicable QA program requirements, the data may be obtained through a non-Q procurement action, provided:

1. Prior review and approval by the responsible OCRWM line organization director and the Director, Office of Quality Assurance, is obtained.

2. Planning for data acquisition and use is performed in accordance with Supplement III, Subsection III.2.1.

3. The data produced by the procurement is identified, controlled, and qualified as described in Supplement III, Subsections III.2.3 and III.2.4.

7.2.13 American Society of Mechanical Engineers Section III Code Items

The following requirements relative to suppliers of ASME Section III Code items apply only to items designed and fabricated in accordance with ASME Section III, Rules for Construction of Nuclear Power Plant Components, and do not apply to non-code items that may be supplied by ASME Section III Code suppliers.

A. For the purchase of ASME Section III Code items, editions of ANSI/ASME NQA-1 identified in NRC endorsed or otherwise approved by the NRC versions of the Code may be used for the construction of ASME Section III Code items

when the referenced edition of ANSI/ASME NQA-1 is used in conjunction with other quality assurance, administrative, and reporting requirements contained in the Code. Further, applicable requirements contained in the QARD or supplier's QA program description document shall also be met in conjunction with the ASME Section III Code.

B. When assessing whether a company has an acceptable QA program to enable it to become a supplier, credit may be taken for the fact that ASME has surveyed the ASME Code supplier and issued a Certificate of Authorization or Quality System Certification of the appropriate scope and for the desired location, without performing any additional evaluation of the supplier's QA program.

C. Audits of ASME Code suppliers shall confirm that the suppliers are satisfactorily implementing:

1. Their accredited ASME Code QA program

2. The technical and quality provisions specified in the purchase order

3. The applicable provisions of the QARD or principal contractor's QA program description document

4. Applicable requirements contained in the regulations.

8.0 IDENTIFICATION AND CONTROL OF MATERIAL, PARTS, AND COMPONENTS

8.1 GENERAL

A. This section establishes requirements for the identification and control of items (including consumables and partially fabricated assemblies) to ensure that only correct and accepted items are used or installed.

B. Computer software nonconformances shall be controlled in accordance with Subsection I.2.5.

8.2 REQUIREMENTS

8.2.1 Identification

A. Identification shall be maintained on the items or in documents traceable to the items.

B. Items shall be identified from the time of initial fabrication, or receipt, up to and including installation or end use.

C. Identification shall relate an item to an applicable design or other pertinent specifying document.

D. Correct identification of items shall be verified and documented prior to release for fabrication, assembly, shipping, or installation.

8.2.2 Physical Markings

A. Item identification methods shall include use of physical markings to the maximum extent possible. If physical markings are either impractical or insufficient, other appropriate means shall be employed (i.e., physical separation, labels or tags attached to containers, or procedural control).

B. Physical markings, when used, shall:

1. Be applied using materials and methods that provide a clear and legible identification.

2. Not detrimentally affect the function or service life of the item.

3. Be transferred to each part of an identified item when the item is subdivided.

4. Not be obliterated or hidden by surface treatments, coatings, or after installation unless other means of identification are substituted.

8.2.3 Conditional Requirements

The controls for items shall address the following requirements, as applicable:

A. If codes, standards, or specifications include specific identification or traceability requirements (i.e., identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; specified inspection, test, or other records), the identification and traceability methods shall be specified in specifications.

B. If codes or standards do not include specific identification or traceability requirements, specifications shall specify identification and traceability methods appropriate to the item.

C. If items, including consumables, have a limited calendar (shelf) life, operating life, or operating cycles, their use shall be subjected to methods established to:

   1. Uniquely identify them.

   2. Establish records identifying the calendar (shelf) life, operating life, and/or operating cycles remaining.

   3. Prevent the further use of such items, including consumables, which have reached the end of their calendar (shelf) life, operating life, or operating cycles.

D. If item storage is required, methods shall be established for the control of item identification that is commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:

   1. Maintenance or replacement of markings and identification tags damaged during handling or aging

   2. Protection of identification markings subject to excessive deterioration resulting from environmental exposure or adverse storage conditions

   3. Updating related documentation.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 GENERAL

A. This section establishes the requirements to ensure that special processes, including welding, heat treating, chemical cleaning, and nondestructive testing are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other requirements.

B. Processes performed to acquire or analyze data for scientific investigations (i.e., siting or design input) are performed in accordance with Supplement III.

9.2 REQUIREMENTS

9.2.1 Special Processes

A. For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualification of personnel, procedures, or equipment shall be specified or referenced in implementing documents.

B. Processes to be controlled as special processes shall meet the following criteria:

1. The results are highly dependent on the control of the process.

2. The results are highly dependent on the skill of the operator.

3. Quality of the results cannot be readily determined by inspection or test of the item.

9.2.2 Personnel, Implementing Documents, and Equipment Qualifications

Implementing documents shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Special process implementing documents shall include or reference:

A. Organizational responsibilities, including those for the QA organization, for the qualification of special process equipment and personnel.

B. Provisions for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

C. Qualification requirements for personnel, implementing documents, and equipment. Certificates of qualification shall clearly delineate the specific processes that personnel are qualified to perform and the criteria used to qualify personnel in each process.

D. Conditions necessary for accomplishment of the special process. These conditions shall include proper equipment, controlled parameters of the process, calibration requirements, and traceability between the item and the individual performing the special process.

E. Requirements of applicable codes, standards, and specifications, including acceptance criteria for the special process.

F. A requirement for the QA organization to be involved in special process personnel, equipment, and process qualification to ensure satisfactory performance. This involvement includes, but is not limited to the performance of surveillances and audits.

9.2.3 Qualification and Certification of Nondestructive Examination Personnel

A. Nondestructive examination shall include radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, acoustic emission, and leak testing.

B. Personnel who perform nondestructive examinations shall be qualified and certified in accordance with Subsection 2.2.11. In lieu of the three-year recertification interval specified in *Recommended Practice No. SNT-TC-1A*, June 1980 Edition, Level III nondestructive examination personnel may be recertified on a five-year interval.

C. Suppliers, other than principal contractors, may qualify their nondestructive examination personnel to other editions of the *Recommended Practice No. SNT-TC-1A*, provided other editions are reconciled to the 1980 edition of the *Recommended Practice No. SNT-TC-1A* and found acceptable to the OQA.

D. Implementing documents shall be established for the control and administration of nondestructive examination personnel training, examination, and certification.

10.0 INSPECTION

10.1 GENERAL

This section establishes requirements for developing an effective inspection program that verifies conformance of items and activities to specified requirements through planning and executing inspections.

10.2 REQUIREMENTS

10.2.1 Inspection Planning

A. Inspection planning shall be performed and documented. Inspection plans may be separate documents governed by procedural controls, or an integral part of approved implementing documents.

B. Representatives of the interested technical organizations and the QA organization shall participate in planning activities.

C. Related codes, standards, specifications, and design documents shall be used to develop inspection plans.

D. The elements of inspection plans identify:

1. Characteristics to be inspected

2. Description of inspection or process monitoring that will be used

3. Identification of the organization responsible for performing the inspection

4. Acceptance criteria

5. Measuring and test equipment to be used to perform the inspection to ensure the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function

6. If applicable, identification of a sampling plan in accordance with Subsection 10.2.4

7. Methods to record inspection results.

10.2.2 Selecting Inspection Personnel to Perform Inspections

A. The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to the requirements of this section.

B. Data recorders, equipment operators, or other inspection or test team members who are supervised by a qualified inspector shall not be required to be a qualified inspector.

C. Inspections shall be performed by individuals other than those who performed the activity being inspected, and those individuals shall not report directly to the supervisor immediately responsible for performance of the work.

10.2.3 Inspection Hold Points

A. When mandatory hold points are used to control work that shall not proceed without the specific consent of the organization placing the hold point, then the specific hold points shall be indicated in implementing documents.

B. Consent to waive specified hold points shall be documented before continuing work beyond the designated hold point.

10.2.4 Statistical Sampling

When statistical sampling is used to verify the acceptability of a group of items, the statistical sampling method shall be based on recognized standard practices and shall comply with the sampling plan requirements delineated in Section 3.0.

10.2.5 In-Process Inspections and Monitoring

A. Items in-process or under construction shall be inspected when necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.

B. Inspection and process monitoring both shall be conducted when control is inadequate with only one method.

C. A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process.

D. Controls shall be established and documented for the coordination and sequencing of the work at established inspection points during successive stages of the process or construction.

10.2.6 Final Inspection

A. Finished items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics, as required to verify the quality and conformance of the item to specified requirements.

B. Quality records not previously examined shall be examined for adequacy and completeness.

C. Final inspections shall include a review of the results and resolution of nonconformances identified by earlier inspections.

D. Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

10.2.7 Accepting Items

A. The acceptance of inspection results shall be documented and approved by qualified and authorized personnel.

B. The inspection status of an item shall be identified according to Section 14.0.

10.2.8 Inspection Documentation

Inspection documentation shall identify:

A. The item inspected

B. The date of inspection

C. The name or unique identifier of the inspector who documented, evaluated, and determined acceptability

D. The name of the data recorder, as applicable

E. The type of observation or method of inspection

F. The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance

G. Results indicating acceptability of characteristics inspected

H. Measuring and test equipment used during the inspection, including the identification number and the most recent calibration date

I. Reference to information on actions taken in connection with nonconformances, as applicable.

10.2.9 Qualification and Certification of Inspection Personnel

Personnel who perform inspections shall be qualified and certified in accordance with Subsection 2.2.11.

11.0 TEST CONTROL

11.1 GENERAL

A. This section establishes requirements for planning and executing tests required to demonstrate that items will perform satisfactorily in service.

1. Tests shall be performed in accordance with implementing documents that incorporate requirements and acceptance criteria contained in applicable design documents.

2. Examples of such tests include: prototype, component, or feature qualification tests; production tests; proof tests prior to installation; construction tests; and preoperational tests (i.e., the test program before the start of preclosure operations).

B. Testing of computer software supporting a safety or waste isolation function shall be performed in accordance with Supplement I.

C. Tests supporting the acquisition of data from samples, and scientific investigation shall be performed in accordance with Supplement III.

11.2 REQUIREMENTS

11.2.1 Test Planning

Test planning shall require that test implementing documents provide for the following:

A. Identification of the implementing documents to be developed to control and perform tests and provide criteria for (i) determining the accuracy requirements of test equipment and (ii) determining when tests are required and defining how and when testing activities are performed

B. Provisions for performing prototype, component, or feature qualification testing, including design verification testing, as early as possible before the installation would become irreversible

C. Identification of the item to be tested and the test requirements and acceptance limits contained in applicable design and procurement documents

D. Identification of test methods to be employed and instructions for performing the test

E. Test prerequisites that address the following: calibrated instrumentation; appropriate and adequate test equipment and instrumentation, including accuracy requirements, trained personnel, condition of test equipment, and the

completeness of the item to be tested; suitably controlled environmental conditions; and provisions for data acquisition and storage

F. Mandatory inspection hold points for witnessing by the organization placing the hold point

G. Methods to record data and results

H. Provisions for ensuring that test prerequisites have been met

I. Selection and identification of the measuring and test equipment to be used to perform the test to ensure that the measuring and test equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function.

11.2.2 Performing Tests

Tests shall be performed in accordance with implementing documents that address the following requirements, as applicable:

A. Provisions for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel

B. Inclusion of or reference to test objectives and provisions for ensuring that prerequisites for the given test have been met, adequate calibrated instrumentation is available and used, necessary monitoring is performed, and suitable environmental conditions are maintained

C. Test requirements and acceptance criteria provided or approved by the organization responsible for the design of the item to be tested, unless otherwise designated

D. Test requirements and acceptance criteria based upon specified requirements contained in applicable design or other pertinent technical documents.

11.2.3 Use of Other Testing Documents

A. Other testing documents (i.e., American Society for Testing and Materials specifications, supplier manuals, equipment maintenance instructions, controlled drawings, or other related documents containing acceptance criteria) may be used instead of preparing special test implementing documents. If used, these documents shall incorporate the information directly into the approved test document governing the test.

B. Other testing documents shall include adequate supplemental instructions, as required, to ensure the required quality of the testing work.

11.2.4 Test Results

A. Test results shall be documented, and their conformance with acceptance criteria shall be evaluated, by a qualified individual within the responsible organization to ensure that test requirements have been satisfied.

B. The test status of an item shall be identified in accordance with Section 14.0.

11.2.5 Test Documentation

Test documentation shall identify the following:

A. Item or work product tested

B. Date of test

C. Name of the tester and data recorders

D. Type of observation

E. Identification of test criteria or reference documents used to determine acceptance

F. Results and acceptability of the test

G. Actions taken in connection with any nonconformances noted

H. Name of the person evaluating and accepting the test results

I. Identification of the measuring and test equipment used during the test, including the identification number and the next calibration due date.

11.2.6 Qualification and Certification of Test Personnel

Personnel who direct tests shall be qualified and certified according to the requirements of Subsection 2.2.11.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 GENERAL

This section prescribes requirements applicable to the establishment of measures that ensure tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

12.2 REQUIREMENTS

12.2.1 Calibration

A. Measuring and test equipment (M&TE), including equipment that contains software or programmable hardware, shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, or prior to use, against reference calibration or transfer standards having traceability to nationally recognized standards. Software developed or modified by the user shall be controlled in accordance with Supplement I. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented.

B. Calibration standards shall have a **greater** accuracy than the required accuracy of standards being calibrated.

1. If calibration standards with a greater accuracy than required of the standard being calibrated do not exist or are unavailable, calibration standards with accuracy **equal to** the required calibration accuracy may be used if they can be shown to be adequate for the requirements.

2. The basis for the calibration acceptance shall be documented and authorized by responsible management. The level of management authorized to perform this function shall be identified.

C. Calibration standards used for the calibration of M&TE shall have an accuracy of at least **four times** the required accuracy of the equipment being calibrated or, when this is not possible, shall have an accuracy that ensures that the equipment being calibrated will be within required tolerance. The basis of acceptance shall be approved by responsible management. The level of management authorized to perform this function shall be identified.

D. The method and interval of calibration for each device shall be defined based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of use, and other conditions affecting measurement control. For M&TE used in one-time-only applications, the calibration shall be done both before and after use.

E. A calibration or calibration check shall be performed:

1. When the accuracy of calibrated in-service M&TE is suspect
2. When calibrated M&TE is removed from service (i.e., retired or surplus).

F. Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date of the next calibration.

G. Calibrated M&TE shall be uniquely identified to provide traceability to its calibration data.

H. Updates to software contained in M&TE that affect calibration shall require recalibration of the equipment prior to use.

12.2.2 Documenting the Use of Measuring and Test Equipment

A. The use of M&TE shall be documented.

B. Selection of M&TE shall be controlled to ensure that such items are of proper type, range, accuracy, and tolerance to accomplish the functions of determining conformance to specified requirements.

C. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration.

12.2.3 Out-of-Calibration Measuring and Test Equipment

A. M&TE shall be considered to be out-of-calibration and shall not be used until calibrated if any of the following conditions exist:

1. The calibration due date or interval has passed without recalibration.
2. The device produces results known to be in error.
3. The calibration status cannot be determined.

B. Out-of-calibration M&TE shall be controlled. The controls shall include the following requirements:

1. Out-of-calibration M&TE shall be tagged, segregated, or otherwise controlled to prevent use until it has been recalibrated.

2. When M&TE is found to be out-of-calibration during recalibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.

   a. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested.

b. The evaluation shall be documented.

c. If evaluation determines that processes monitored or items inspected or tested are suspect, it shall be documented in accordance with Section 15.0. Inspections or tests shall be repeated for items determined to be suspect.

C. If M&TE is consistently found to be out-of-calibration during the recalibration process, it shall be repaired or replaced.

12.2.4 Lost Measuring and Test Equipment

When M&TE is lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.

A. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested.

B. The evaluation shall be documented.

C. If evaluation determines that processes monitored or items inspected or tested are suspect, it shall be documented in accordance with Section 15.0.

12.2.5 Handling, Storage, and Use

A. M&TE shall be properly handled and stored to maintain accuracy.

B. Selection of M&TE shall be controlled to ensure that such items are the proper type for the intended use.

12.2.6 Commercial Devices

Calibration and control shall not be required for rulers, tape measures, levels, and other normal commercial equipment that provides adequate accuracy.

12.2.7 Measuring and Test Equipment Documentation

M&TE calibration documentation shall include the following information:

A. Identification of the measuring or test equipment calibrated

B. Traceability to the calibration standard used for calibration

C. Calibration data

D. Identification of the individual performing the calibration

E. Identification of the date of calibration and the recalibration due date or interval, as appropriate

F. Results of the calibration and statement of acceptability

G. Reference to any actions taken in connection with out-of-calibration or nonconforming M&TE, including evaluation results and repeated inspections or tests, as appropriate

H. Identification of the implementing document (including revision level) used in performing the calibration.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 GENERAL

This section establishes requirements for the handling, storage, cleaning, packaging, shipping, and preservation of items and consumables, in accordance with design and procurement requirements, to prevent damage or loss and to minimize deterioration.

13.2 REQUIREMENTS

13.2.1 Controls

A. Handling, storage, cleaning, packaging, shipping, and preservation of items shall be conducted in accordance with established work and inspection implementing documents, shipping instructions, or other specified documents.

B. If required for critical, sensitive, perishable, or high-value articles, specific implementing documents for handling, storage, cleaning, packaging, shipping, and preservation shall be prepared and used.

13.2.2 Special Equipment, Tools, and Environments

A. If required for particular items, special equipment (e.g., containers, shock absorbers, and accelerometers) and special protective environments (i.e., inert gas and specific moisture and temperature levels) shall be specified and provided.

B. If special equipment and environments are used, provisions shall be made for their verification.

C. Special handling tools and equipment shall be used and controlled, as necessary, to ensure safe and adequate handling.

D. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with implementing documents to verify that the tools and equipment are adequately maintained.

E. Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

13.2.3 Marking and Labeling

A. Measures shall be established for marking and labeling for the packaging, shipping, handling, and storage of items as necessary to adequately identify, maintain, and preserve the item.

B. Markings and labels shall indicate the presence of special environments or the need for special controls, if necessary.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 GENERAL

This section establishes requirements to identify the inspection, test, and operating status of items throughout fabrication, construction, installation, and testing.

14.2 REQUIREMENTS

14.2.1 Identifying Items

A. Items that have satisfactorily passed required inspections and tests shall be identified.

B. The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed required inspections and tests.

14.2.2 Indicating Status

A. The status of required inspection and tests of items shall be indicated when necessary to preclude inadvertent bypassing of such inspections and tests.

B. The status of inspections and tests shall be identified either on the items or in documents traceable to the items.

C. Status shall be maintained through the use of legible and easily recognizable status indicators (i.e., tags, markings, labels, and stamps) or other means (i.e., travelers, inspection, or test records).

D. The authority for applying and removing status indicators shall be specified.

E. To prevent the inadvertent use or operation of an item that is out of service (e.g., a nonconforming, inoperative, or malfunctioning item), status indicators, such as tags or markings, shall be placed at all locations where operation of the item can be initiated, such as control panels, switches, breakers, valves, or systems.

15.0 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

15.1 GENERAL

A. This section establishes requirements for the control of items (including samples, boreholes, services, etc.) that do not conform to requirements in order to prevent inadvertent installation or use of the item.

B. Computer software nonconformances shall be controlled in accordance with Subsection I.2.5.

15.2 REQUIREMENTS

15.2.1 Documenting, Reporting, and Evaluating Nonconforming Items

A. Nonconformances shall be documented and reported to the appropriate levels of management responsible for the conditions. In addition, organizations affected by the nonconformance shall be notified.

B. Nonconformances shall be tracked and trended in accordance with the requirements of Section 16.0.

C. Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.

D. Nonconformance documentation shall be reviewed, and recommended dispositions of nonconforming items shall be proposed. The review shall include determining the need for corrective action according to the requirements of Section 16.0.

E. Recommended dispositions shall be evaluated and approved by individuals who are independent of the work that produced the disposition.

F. Personnel performing evaluations to determine a disposition as well as those evaluating a recommended disposition shall have demonstrated competence in the specific area being evaluated, have an adequate understanding of the requirements, and access to pertinent background information.

G. The responsibility and authority for reviewing, evaluating, and approving the disposition, and closing nonconformances shall be specified.

H. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition.

I. Nonconformances shall be corrected or dispositioned before initiation of the preoperational test program on the item.

15.2.2 Identifying Nonconforming Items

A. Nonconforming items shall be identified by marking, tagging, or other methods that do not adversely affect their end use. The identification shall be legible and easily recognizable.

B. If the identification of a nonconforming item is not practical, then the container, package, or segregated storage area, as appropriate, shall be identified.

15.2.3 Segregating Nonconforming Items

A. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

B. If segregation is impractical or impossible due to physical conditions, other precautions shall be employed to preclude inadvertent use.

15.2.4 Disposition of Nonconforming Items

A. The disposition of "use-as-is," "limited use" (this disposition is limited to Supplement II nonconforming samples), "reject," "repair," or "rework" for nonconforming items shall be identified and documented.

B. The technical justification for the acceptability of a nonconforming item that has been dispositioned "repair," "limited use," or "use-as-is" shall be documented.

C. Items that do not meet original design requirements that are dispositioned "use-as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design.

1. If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance.

2. Any document or QA record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation, and when each document or record is changed, the justification for the change shall identify the nonconformance documentation.

D. The disposition of an item to be reworked or repaired shall contain a requirement to reexamine (i.e., inspect, test, or nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be reexamined using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

E. Replacement items shall be inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives.

16.0 CORRECTIVE ACTION

16.1 GENERAL

This section establishes requirements to ensure conditions adverse to quality are promptly identified and corrected as soon as practical.

16.2 REQUIREMENTS

16.2.1 Identifying Conditions Adverse to Quality

A condition adverse to quality shall be identified when a failure, malfunction, deficiency, defective item, or nonconformance is identified.

16.2.2 Classification of Conditions Adverse to Quality

A. Conditions adverse to quality shall be classified in regard to their significance, and corrective actions shall be taken accordingly.

B. Categories of classification shall be established to distinguish between:

1. Conditions adverse to quality
2. Significant conditions adverse to quality.

16.2.3 Conditions Adverse to Quality

A. Conditions adverse to quality shall be documented, tracked, and reported to the appropriate levels of management responsible for the conditions.

B. Responsible management shall determine the extent of the adverse condition and complete remedial action as soon as practical.

16.2.4 Significant Conditions Adverse to Quality

A. Criteria for determining a significant condition adverse to quality shall be established.

B. Significant conditions adverse to quality shall be documented and reported to management responsible for the condition and their upper management.

C. Significant conditions adverse to quality shall be evaluated for a stop work condition by the QA organization to determine whether stopping work is warranted.

1. QA management shall issue stop work orders to responsible management after a stop work condition has been identified.

2. QA management shall take appropriate action to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality.

D. Responsible management shall perform investigative action to determine the extent and impact of the condition, and document the results.

E. Responsible management shall determine, document, and complete remedial action.

F. Responsible management shall determine the root cause of the problem and take corrective action to prevent recurrence as soon as practical.

16.2.5 Follow-up

Processes shall be established to verify the implementation of corrective actions prior to closeout of the documentation associated with conditions adverse to quality.

16.2.6 Quality Trending

A. Criteria shall be established for determining adverse quality trends.

B. Reports of nonconformances and conditions adverse to quality shall be evaluated to identify adverse quality trends.

C. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends and assist in identifying root cause.

D. Trend evaluations shall be promptly distributed to OCRWM and OCRWM contractor management for review and appropriate corrective action.

17.0 QUALITY ASSURANCE RECORDS

17.1 GENERAL

A. This section establishes requirements to ensure that QA records that furnish documentary evidence of quality are specified, prepared, and maintained. The records system shall be established at the earliest practicable time consistent with the schedule for accomplishing activities affecting quality.

B. The requirements of this section that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

17.2 REQUIREMENTS

17.2.1 Quality Assurance Records

A. Specific QA record types include, but are not limited to:

1. Scientific, engineering, and operational data and logs; laboratory and field notebooks and logbooks; and data reduction documents

2. Results of reviews, inspections, tests, audits, and material analysis

3. Monitoring of work performance

4. Maintenance and modification procedures and related inspection results

5. Reportable occurrences

6. QA program changes that reduce commitments

7. Computer software supporting a safety or waste isolation function

8. Qualification of personnel, procedures, and equipment

9. Documentation such as design records, drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, corrective action reports, and as-built drawings

10. Other records required by preclosure and postclosure operating conditions

11. Construction records required by 10 CFR 63.72.

B. Additional guidance relative to the types of documents considered to be QA records is provided in ANSI/ASME NQA-1-1983, Appendix 17A-1, and NRC Regulatory Guide 1.28, Revision 3.

17.2.2 Creating Valid Quality Assurance Records

A. Implementing documents shall:

1. Identify those documents that will become QA records.

2. Identify the organization responsible for submitting the QA records to the records management system.

B. Individuals creating QA records shall ensure that the QA records are legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply.

C. Individuals handling QA records shall protect them from damage or loss until the records are submitted to the records management system.

D. Documents shall be considered valid records when stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated as complete. This authentication may take the form of a statement by the reporting individual or organization. If the nature of the record (i.e., magnetic or optical media) precludes stamping, initialing, or signing, then other means of identifying the record as complete by authorized personnel are permitted.

E. Handwritten signatures shall not be required if the document is clearly identified as a statement of the reporting individual or organization.

F. QA records may be originals or copies.

17.2.3 Submission of Quality Assurance Records

QA records shall be submitted to the records management system for receipt, processing, and storage.

17.2.4 Receiving and Indexing Quality Assurance Records

A receipt control system shall be established for QA records according to the following requirements:

A. An individual or organization shall be assigned the responsibility for receiving QA records. The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.

B. A method shall be established for verifying that the QA records received are in agreement with the transmittal document.

C. QA records shall be protected from damage, deterioration, or loss when received.

D. Legibility and completeness of QA records shall be verified.

E. The receipt control system shall permit a current and accurate assessment of the status of QA records during processing.

F. QA records shall be indexed to ensure retrievability. The indexing system shall include:

1. The location of the QA records within the records management system
2. Identification of the item or related activity to which the QA records pertain
3. The record retention times.

17.2.5 Correcting Information in Quality Assurance Records

A. Corrections to QA records, including documents that will become QA records, shall include the initials or signature of the person authorized to make the correction and the date the correction was made.

B. Corrections to QA records shall be approved by the originating organization. If the organization responsible for generating the record is no longer available, a new responsible organization shall be identified.

17.2.6 Storing and Preserving Quality Assurance Records

A. QA records shall be stored and preserved in predetermined storage facilities in accordance with an approved implementing document that provides:

1. A description of the storage facility

2. A description of the filing system to be used

3. A method for verifying that the QA records received are in agreement with the transmittal document and that the records are legible

4. A description of controls governing QA record access, retrieval, and removal

5. A method for filing supplemental information

6. A method for disposition of superseded QA records.

B. Storage methods shall be developed to preclude deterioration of QA records in accordance with the following:

1. The storage area shall minimize the risk of damage or destruction by natural disasters, extremes in environmental conditions, and infestations of pests or molds.

2. Approved filing methods shall require QA records to be firmly attached in binders or placed in folders or envelopes, for storage in steel file cabinets or on shelving in containers appropriate for the QA record medium being stored.

3. The storage arrangement shall provide adequate protection of special processed QA records (i.e., radiographs, photographs, negatives, microform, and electronic and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of QA record being stored. The guidance provided in NRC Regulatory Issue Summary 2000-18, *Guidance on Managing Quality Assurance Records in Electronic Media*, shall be complied with in the development of procedures governing the management of electronic media records.

4. The storage area shall be protected from unauthorized entry, larceny, and vandalism.

17.2.7 Retrieval of Quality Assurance Records

A. The records management system shall provide for retrieval of QA records.

B. Access to storage facilities shall be controlled. A list shall be maintained designating personnel who are permitted access to the QA records.

17.2.8 Retention of Quality Assurance Records

A. Retention of OCRWM QA records shall be in accordance with the retention and disposition instructions contained in a records retention schedule.

B. The retention periods delineated in the records retention schedule shall meet or exceed the retention requirements delineated in ANSI/ASME NQA-1-1983 and NRC Regulatory Guide 1.28, Revision 3. At a minimum, QA records shall be maintained until the end of the operating period.

C. Records retained by suppliers shall be retained in accordance with procurement document requirements. Records shall be made available to the OCRWM or its designee upon request.

17.2.9 Turnover of Quality Assurance Records

A. Suppliers shall submit, to the OCRWM, those QA records being temporarily stored by supplier that are subject to records turnover requirements. The timing of the submittal shall be as records packages become complete or, as items are released for shipment, or as prescribed by the purchaser.

B. The records management organization shall inventory the submittal, acknowledge receipt, and process the QA records.

C. The responsible line organizations shall identify those QA records in temporary storage to be submitted for long-term storage to the records management system in accordance with Subsection 17.2.10, or Subsection 17.2.11.

17.2.10 Long-Term Single Storage Facility

A. Single storage facilities for the storage of QA records shall meet the following design and construction requirements:

1. Reinforced concrete, concrete block, masonry, or equal construction.

2. Floor and roof with drainage control. If a floor drain is provided, a check valve or equal shall be included.

3. Minimum 2-hour fire-rated structure, doors, and frames.

4. Sealant applied over walls as a moisture or condensation barrier.

5. Surface sealant on floor providing a hard wear surface to minimize concrete dusting.

6. Foundation sealant and provisions for drainage.

7. Forced air circulation with filter system.

8. Fire protection system.

9. Penetrations limited to fire protection, communication, lighting, and temperature and humidity controls. Seal or damper penetrations to meet 2-hour fire protection rating.

B. If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of the criteria in Paragraph 17.2.10A.

C. Construction details shall be reviewed for the adequacy of record protection by a person competent in the technical field of fire protection and fire extinguishing.

17.2.11 Dual Storage Facilities

A. Dual storage facilities for the storage of QA records shall provide facilities for copies of each record at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

B. Dual storage facilities shall not be required to meet the design and construction requirements specific for a long-term single storage facility.

17.2.12 Temporary Storage Facility

Temporary storage shall provide for the storage of QA records during processing, review, or use until turnover to the OCRWM for disposition according to the following requirements:

A. QA records shall be temporarily stored in a container or facility with a fire rating of 1-hour, or dual storage shall be provided.

B. Single storage containers or facilities shall bear an Underwriters' Laboratories label (or equivalent) certifying 1-hour fire protection or be certified by a person competent in the technical field of fire protection.

C. Procedures shall specify the maximum allowable time for the temporary storage of QA records.

17.2.13 Replacement of Quality Assurance Records

Organizations originating QA records shall develop implementing documents that identify means for replacement, restoration, or substitution of lost or damaged QA records.

18.0 AUDITS

18.1 GENERAL

A. This section establishes requirements for performing a comprehensive system of planned and periodic internal and external QA audits to verify compliance with all aspects of the OCRWM QA program, and to determine the effectiveness of the OCRWM QA program.

B. The requirements of this section that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

18.2 REQUIREMENTS

18.2.1 Audit Scheduling

Audits shall be performed in all areas where the requirements of the QARD or supplier's QA program description document are applicable. The following areas shall also be considered when scheduling audits:

A. The determination of site features that effect site safety (e.g., site characterization, performance confirmation, core sampling, site and foundation preparation, and methodology)

B. The preparation, review, approval, and control of early procurements

C. Indoctrination and training programs

D. Interface control between the OCRWM and suppliers

E. Corrective action, calibration, and nonconformance control systems

F. Safety Analysis Report commitments

G. Development and control of computer software supporting a safety or waste isolation function

H. The purchase of ASME Code items

I. Audits of ASME Code suppliers.

18.2.2 Scheduling Internal Audits

A. Internal audits shall be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.

B. Internal audits shall be scheduled at a frequency commensurate with the status and importance of the work.

C. Internal audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work.

D. Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects, when necessary, to provide an adequate assessment of compliance and effectiveness.

E. Internal audits of applicable QARD elements to verify OCRWM QA program compliance and effectiveness shall be performed at intervals not to exceed 12 months or at least once during the life of the work, whichever is shorter.

F. Performance-based internal audits shall be performed on selected work to determine OCRWM QA program effectiveness.

18.2.3 Scheduling External Audits

A. External audits (audits of suppliers) shall be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.

B. External audits shall be scheduled:

1. To begin as early in the life of the work as practical.

2. To continue at intervals consistent with the schedule for accomplishing the work.

3. At a frequency commensurate with the status and importance of the work.

C. External supplier audits for compliance and effectiveness shall be performed triennially or at least once during the life of the work, whichever is shorter. Audits of principal contractors, for compliance and effectiveness, shall be performed at intervals not to exceed 12 months or at least once during the life of the work, whichever is shorter. Regularly scheduled external audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness (performance based).

1. The audit period (triennial or annual) shall begin when the audit is performed.

2. The initial audit shall be performed when the supplier has completed sufficient work to demonstrate that its organization is implementing a QA

program that has the required scope for purchases placed during the audit period (triennial or annual).

3. An audit of the modified requirements shall be performed when a major change in the contract scope, work methodology, or organization occurs. This audit shall start a new audit period (triennial or annual).

D. Performance-based external audits shall be performed on selected work to determine QA program effectiveness.

E. External audits may not be required for procured items that are relatively simple and standard in design, manufacturing, and testing, and adaptable to standard or automated inspections or tests of the end item to verify quality characteristics after delivery. Rationale for not performing audits for these items shall be documented.

F. Pre-award surveys, if applicable, may serve as the first triennial audit, provided:

1. The supplier is implementing the same QA program for other contracts that is proposed for the purchaser's contract.

2. The pre-award survey satisfies the same audit elements and criteria as those used in the performance of a triennial audit.

G. OCRWM purchasers include the OCRWM and OCRWM contractors. If more than one OCRWM purchaser buys from a single supplier, the OCRWM purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other OCRWM purchasers to reduce the number of external audits of the supplier.

1. The scope of this audit shall satisfy the needs of all OCRWM purchasers having a need to use the supplier.

2. The audit report shall be distributed to all OCRWM purchasers for whom the audit was conducted.

3. Each OCRWM purchaser relying on the results of the audit shall be responsible for the adequacy of the audit.

18.2.4 Audit Schedule

The audit schedule(s) shall be developed annually and revised periodically to ensure that coverage is maintained current.

18.2.5 Audit Planning

A. The auditing organization shall develop and document an audit plan for each scheduled audit. This plan shall identify the audit scope, requirements for performing the audit, audit personnel, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used. Audits shall include technical evaluations of the applicable procedures, instructions, activities, and items.

B. The scope of each internal audit shall be based on evaluation of implementing documents, activities, and items to be audited; results of previous audits; nature and frequency of previously identified deficiencies; and impact of significant changes in personnel, organization, or the QA program.

18.2.6 Audit Team Independence

The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activity being audited. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

18.2.7 Audit Team Selection

A. An audit team shall be identified before beginning each audit. The audit team shall include representatives from the QA organization, and when appropriate, applicable technical specialists.

B. A lead auditor shall be appointed to supervise the team, organize and direct the audit, and coordinate the preparation and issuance of the audit report.

C. Lead auditors and auditors shall be qualified in accordance with the requirements of this section.

D. Technical specialists may be used by the auditing organization to assist in assessing the adequacy of technical processes. Technical specialists, when used, shall be indoctrinated and trained in accordance with Subsection 18.2.13.

. E. In the case of internal audits, personnel having direct responsibility for performing the work being audited shall not be involved in the selection of the audit team.

F. The lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited.

18.2.8 Performing Audits

A. The audit team leader shall ensure that the audit team is prepared before starting the audit.

B. Audits shall be performed in accordance with written procedures or checklists.

C. Elements that have been selected for audit shall be evaluated against specified requirements.

D. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively.

E. Audit results shall be documented by auditing personnel and reported to and reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

F. Identified conditions adverse to quality shall be documented and corrected in accordance with Section 16.0.

18.2.9 Reporting Audit Results

The audit report shall be prepared and signed by the audit team leader, and issued to management of the audited organization. The audit report shall include the following information:

A. A description of the audit scope

B. Identification of the auditors

C. Identification of persons contacted during the audit

D. Summary of the audit results including a statement on the effectiveness of the QA program elements that were audited

E. A description of each reported condition adverse to quality in sufficient detail to enable corrective action to be taken by the audited organization according to the requirements of Section 16.0.

18.2.10 Responding to Audits

A. Management of the internal audited organization, including principal contractors, shall investigate conditions adverse to quality and determine and schedule corrective action in accordance with Section 16.0.

B. Management of the external audited organization (other than principal contractors) shall investigate conditions adverse to quality, determine and schedule corrective action in accordance with Section 16.0, and notify the auditing organization in writing of the actions taken or planned.

18.2.11 Evaluating Audit Responses

The adequacy of corrective actions for conditions adverse to quality shall be evaluated by the auditing organization.

18.2.12 Follow-up Action

Follow-up action shall be taken by the auditing organization to verify that corrective action is accomplished as scheduled.

18.2.13 Audit Team Qualification and Certification

Personnel performing audits, including auditors, technical specialists, and lead auditors shall be qualified and certified in accordance with Subsection 2.2.11.

SUPPLEMENT I SOFTWARE

I.1 GENERAL

A. This supplement establishes requirements for the acquisition, development, modification, control, and use of software.

B. Requirements of this supplement shall be implemented through policies, procedures, plans, specifications, work practices, etc., that provide the framework for software engineering activities. Software engineering elements must define the baseline documents that are to be maintained as records. The scope of software engineering activities includes the following elements, as appropriate:

1. Software acquisition method(s) for controlling the acquisition process for software and software services

2. Software engineering method(s) used to manage the software life cycle activities

3. Application of standards, conventions, and other work practices that support the software life cycle

4. Controls for support software used to develop, operate, and maintain computer programs.

C. Embedded software that is integral to the operations, maintenance, or calibration of M&TE that is verified or validated in conjunction with hardware as a unit and has not been developed or modified by the user organization is controlled by Section 12.0, and is exempt from the requirements of this supplement.

D. The following types of commercial off-the-shelf (COTS) software are not required to be qualified using this supplement: word processors, spreadsheets, database managers, e-mail, and other types of automated office support systems. Applications developed using these types of COTS software shall meet the requirements of this supplement.

E. COTS support software, such as software tools or system software, shall, at a minimum, be evaluated, reviewed, tested, accepted for use, and placed under configuration control as part of the supported software development. Changes to the software tool and system software shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

F. The requirements of this supplement that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

I.2 REQUIREMENTS

I.2.1 General Software Requirements

A. Software acquisition, development, modification, and maintenance shall proceed in a planned, traceable, and orderly manner utilizing a defined software life cycle methodology.

1. A defined software life cycle methodology shall address the following phases: requirements, design, implementation, testing, installation and checkout, operations and maintenance, and retirement. The number of phases and relative emphasis placed on each phase of the software life cycle depend on the nature and complexity of the software. The number of life cycle phases may be combined for documentation purposes; however, the combining of phases does not eliminate the requirement for addressing each life cycle element of the life cycle phase. Software life cycle activities may be performed in an iterative or sequential manner.

2. Acquired software or software previously developed not using this supplement shall be either:

   a. Acquired through a procurement activity in accordance with Subsection I.2.6, with appropriate quality controls, or

   b. Be controlled and qualified in accordance with Subsection I.2.7.

   In either case, software planning in accordance with Subsection I.2.2, and a defined software life cycle methodology, excluding a design document and code development, shall be applied.

3. Software life cycles shall contain control points that, when reached, shall ensure specified software is documented, reviewed, and baselined.

B. Software verification and validation activities shall be planned, documented, and performed for software, software changes, or system configurations that are determined to impact the software. The validation test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the software.

1. Software verification shall be performed at the end of the requirements, design, implementation, and testing life cycle phases to ensure that the products of a given life cycle phase are traceable and fulfill the requirements of the previous phase and/or previous phases.

2. Software verification shall evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and

correctness of the software and shall verify that software is traceable to the software design requirements.

a. Tests and test results from reviews and verifications shall be included in the acceptance test documentation.

b. Tests conducted as reviews or verifications do not substitute for performing comprehensive, end-of-development acceptance tests.

3. Software verification shall include review of the test results.

4. Software verification shall be completed prior to approval of the computer program for use.

5. Verification reviews shall identify the reviewer(s) and each reviewer's specific responsibilities during the review.

6. Documentation of all review comments and their disposition shall be retained as part of the records package.

7. Software verification and validation activities shall be performed by individuals not associated with the development of the software. In those instances where this level of independence may not be achieved, an individual associated with the development of the software may perform these activities with a higher level of management approval and documented justification.

I.2.2 Software Planning

A. A plan addressing software quality assurance shall be in existence for each new software project at the start of the software life cycle.

B. The plan for software quality assurance shall identify:

1. A description of the overall nature and purpose of the software

2. The software products to which it applies

3. The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities

4. Required documentation

5. Standards, conventions, techniques, or methodologies that shall guide the software activity

6. Required software reviews

7. Methods for error reporting and corrective action.

I.2.3 Software Life Cycle Requirements

A. Requirement Phase

1. Software requirements that address functionality, performance, design constraints, attributes, and external interfaces shall be specified, documented, and reviewed.

   a. Functionality–The functions the software is to perform.

   b. Performance–The time-related issues of software operation such as speed, recovery time, response time, etc.

   c. Design constraints imposed on implementation phase activities–Any elements that will restrict design options.

   d. Attributes–Non-time-related issues of software operation such as portability, acceptance criteria, access control, maintainability, etc.

   e. External interfaces–Interactions with people, hardware, and other software.

2. A software requirement shall only be specified if its achievement can and will be verified and validated.

3. Software requirements shall be traceable throughout the remaining stages of the software life cycle (i.e., design, installation and validation test cases, and user manual). Traceability shall be documented.

4. Software requirements shall provide enough detail to either design the software or make an acquisition decision.

B. Design Phase

1. The software design shall be developed, documented, and reviewed based on the requirements depicted in the requirements document.

2. The software design shall consider the computer software operating environment.

3. Measures to mitigate the consequences of potential problems shall be an integral part of the design. These potential problems include external and

internal abnormal conditions and events that can affect the computer program.

4. The design documentation shall specify:

   a. A description of the major components of the software design as they relate to the software requirements.

   b. A technical description of the software with respect to the theoretical basis, mathematical model, control flow, data flow, control logic, and data structure.

   c. A description of the allowable or defined ranges for inputs and outputs.

   d. The design, described in a manner that can be translated into code.

   e. The generation of design-based test cases.

   f. The generation of test plans/cases, based on the requirements and design, shall provide for acceptance criteria and verification of results.

   g. For those computer programs used in design activities, the test plans shall provide for ensuring that the software produces correct results. For those computer programs used for operational control, computer test plans shall provide for demonstrating required performance over the range of operation of the controlled function or process.

C. Implementation Phase

1. The design shall be translated into source code and resulting executables necessary to perform the functions required.

2. The source code and resulting executables shall adhere to specified coding standards, conventions, and design specifications.

3. User information shall be developed, documented, and reviewed in accordance with the design to delineate how to use the software, including the following, as applicable:

   a. Instructions that contain an introduction (e.g., purpose, scope, etc.), description of the user's interaction with the software, and a description of any required training necessary to use the software

   b. Input and output specifications

   c. Data files, input and output data, defaults, and file formats

d. A description of the allowable and tolerable ranges for inputs and outputs

e. Anticipated errors and how the user can respond

f. The hardware and software environments

g. Available sample problems

h. Installation procedures.

D. Testing Phase

1. Configuration items shall be under configuration change control prior to acceptance testing.

2. Software validation activities shall be planned, performed, documented, and verified at the end of the implementation phase to ensure that the software installs properly and satisfies the requirements for its intended use.

3. Testing, to an approved plan or process and on a different computer with an identical operating environment as that on which it was developed, shall be the primary method of software validation to ensure adherence to the requirements and to ensure the software produces correct results for the test cases.

4. Testing shall demonstrate, as appropriate, that the computer program:

   a. Properly handles abnormal conditions and events as well as failures.

   b. Does not perform adverse unintended functions. Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval.

   c. Does not unexpectedly degrade the system either by itself or in combination with other functions or configuration items.

5. To evaluate technical adequacy, the software test case results may be compared to results from alternative methods, such as:

   a. Analysis without computer assistance (hand calculations)
   b. Other validated computer programs
   c. Experiments and tests
   d. Standard problems with known solutions
   e. Comparisons to confirmed published data correlations.

6. Software validation documentation shall describe the task and criteria for accomplishing the validation of the software at the end of the development cycle. The documentation shall:

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   a. Specify the hardware and software configurations.

   b. Be organized in a manner that allows traceability to both software requirements and design.

   c. Contain the results of the execution of the validation activity.

   d. Include the results of reviews and tests along with a summary of the status of the software (e.g., indication of incomplete design performance and application requirements).

7. Failure to successfully execute the test cases shall be documented and reviewed to determine if modifications to the requirements, design, implementation, or test plans and cases are required.

8. Software validation of modifications to released software shall be subjected to selective testing (e.g., regression) to detect unintended adverse effects introduced during the modification of the software, to verify that the modifications have not caused unintended adverse affects, and to verify that a modified software still meets specified requirements.

E. Operations and Maintenance Phase

1. Upon acceptable validation of the software, in accordance with Paragraph I.2.3.D, Testing Phase, the software shall be baselined and placed under Configuration Management controls in accordance with Subsection I.2.4.

2. After the software is approved for use and installed in the operating environment, the use of the software shall be controlled, in accordance with Subsection I.2.8, within approved procedures and instructions.

3. Further operations and maintenance activities shall consist of maintenance of the software:

   a. To remove latent errors (corrective maintenance)

   b. To respond to new or revised requirements (perfective maintenance)

   c. To adapt the software to changes in the operating environment (adaptive maintenance).

4. Software modifications shall be approved, documented, verified and validated, and controlled.

5. In-use tests shall be developed, performed, documented, and verified to provide confirmation of acceptable performance of software that is performing continuous data acquisition or process control functions. Periodic manual or automatic self-check in-use tests shall be defined and performed for that software where computer program errors, data errors, computer hardware failures, or instrument drift can affect the required performance.

F. Installation and Checkout Phase

1. Software installation and checkout activities shall be performed and documented when the software is installed on a computer or when there are changes in the operating system to ensure that the software installs properly and satisfies the requirements for its intended use.

2. The software validation activities for the installation and checkout shall consist of:

a. The execution of tests for installation

b. The documentation that the software was successfully installed and ready for operational use.

G. Retirement Phase

During the retirement phase, the support for a software product is terminated and continued routine use of the software shall be prevented.

I.2.4 Software Configuration Management

A. A software configuration management (SCM) system shall be established to include configuration identification, configuration change control, and status accounting. Software shall be placed under configuration management control as each baseline element is approved.

B. Software shall not be used in activities identified under Subsection 2.2.2 unless it has been qualified and baselined. Software used in activities affecting quality is limited to copies obtained from SCM.

C. Support software (i.e., systems software and software tools) is not qualified nor is it baselined. However, such software shall be placed under configuration management control (including change control) by SCM (see Subsection I.1.D).

D. Configuration items to be controlled shall include the following, at a minimum and as appropriate:

1. Documentation (i.e., plans, requirements, designs, user manuals, test reports, user information, etc.)

2. Computer program(s) (i.e., source, object, backup files, media, etc.)

3. Support software.

E. Configuration identification shall include:

1. A definition of the baseline elements of each software baseline.

2. A unique identification of each software item, including version or revision, to be placed under SCM.

3. Assignment of unique identifiers that relate baseline documents to their associated software items. Cross-references between baseline documents and associated software shall be maintained.

F. Configuration change control shall include:

1. A release and control process for baseline elements.

2. Changes to baseline elements. These changes shall be formally controlled and documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected baseline elements.

3. A formal evaluation of the baseline element or change to the baseline element and approval by the organization responsible for approving the baseline element.

4. The transmission of information concerning approved changes to all organizations affected by the changes.

5. Software verifications performed for the changes, as necessary, to ensure the changes are appropriately reflected in software documentation and to ensure that document traceability is maintained.

6. Software validation performed as necessary for the change.

G. Configuration status accounting shall include:

1. A listing of the approved baseline elements and unique identifiers

2. The status of proposed, in-process, or approved changes to the baseline elements

3. A history of changes to the software items, including descriptions of the changes made between versions of software items.

I.2.5 Problem Reporting and Resolution

A. A software problem reporting and resolution system shall be implemented for software errors and failures to ensure problems are promptly reported to impacted organizations and to ensure formal processing of problem resolutions.

B. The problem reporting and resolution system shall be integrated with the SCM system.

C. Software problem reporting and resolution systems shall provide methods to ensure that:

1. Problems are identified, evaluated, documented, and, if required, corrected.

2. Description of the evaluation process for determining if the problem is an error or other type of problem (e.g., user mistake) and define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation is provided.

3. Problems are assessed for impact, which includes:

   a. How the error relates to appropriate software engineering elements
   b. Impact on past and present use of the software by an organization
   c. How the corrective action impacts previous development activities.

4. Corrections and changes shall be controlled in accordance with applicable configuration change control requirements.

5. Notification of the error, its impacts, and how to avoid the error, pending implementation of corrective actions, is provided to the user organizations.

D. If a problem that constitutes a condition adverse to quality is identified in software, the condition adverse to quality shall be documented and controlled in accordance with Section 16.0.

I.2.6 Software Procurement

A. Individuals or organizations developing and supplying software under contract shall be required to have policies and procedures that meet the applicable requirements of this supplement. Software shall be procured as specified in Sections 4.0 and 7.0.

1. Documentation as required by this supplement shall be delivered or made available by the supplier to the purchaser.

2. Upon receipt of the software, the purchaser shall assume responsibility of the applicable requirements as specified in this supplement.

3. Software errors and failures shall be reported between the supplier and purchaser in accordance with Subsection I.2.5.

B. For procured software services, the organization providing the services shall have plan(s) for software quality assurance, in accordance with Paragraph I.2.2.A, that meets the requirements of Subsection I.2.7. The user organization shall determine the adequacy of this plan.

I.2.7 Otherwise Acquired Software

Software that has not been previously approved under a program consistent with this supplement for use in its intended application (e.g., freeware, shareware, procured COTS, or otherwise acquired software), other than software described in Paragraphs I.1C and I.1D, shall be qualified in accordance with the requirements of this supplement. The software shall be identified and controlled in accordance with Subsection I.2.4 prior to qualification.

I.2.8 Control of the Use of Software

A. User organizations control and document the use of released software items such that comparable results can be obtained, with any differences explained, through independent replication of the process.

B. Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.

C. If the intended use of the software item will require the use of inputs outside the ranges verified during validation testing, the appropriate baseline elements shall be reverified and revalidated for the expected range of inputs prior to continuing use.

D. Documentation for the receipt of software obtained from SCM in accordance with Subsection I.2.4 shall be provided and maintained for software in operation or use.

E. Controls shall be established to permit authorized access and prevent unauthorized access to computer systems.

SUPPLEMENT II SAMPLE CONTROL

II.1 GENERAL

This supplement establishes requirements for the control of physical samples.

II.2 REQUIREMENTS

II.2.1 General Requirements

A. Samples shall be controlled and identified in a manner consistent with their intended use.

B. Controls shall identify responsibilities, including interfaces between organizations, for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use.

C. Controls shall include specifics on orientation relative to the location that was sampled, as appropriate.

II.2.2 Traceability

A. Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents.

B. Sample traceability shall ensure that the sample can be traced at all times from its collection through final use and any post-test retention that may be appropriate.

II.2.3 Identification

A. Identification shall be maintained on the samples or in a manner that ensures that identification is established and maintained.

B. Samples shall be identified from their initial collection through final use.

C. Sample identification shall be documented and checked before the sample is released for use or analysis.

D. Sample identification methods shall include use of physical markings.

E. If physical markings are either impractical or insufficient, other appropriate means shall be employed (i.e., physical separation, labels or tags attached to containers, or other procedural control).

F. Physical markings, when used, shall:

1. Be applied using materials and methods that provide a clear and legible identification.

2. Not detrimentally affect the sample content or form.

3. Be transferred to each identified sample part when the sample is subdivided.

4. Not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted.

II.2.4 Conditional Requirements

The controls for samples shall address the following requirements, as applicable:

A. If documents contain specific identification or traceability requirements (i.e., identification or traceability of the sample to applicable study plan, site characterization activity, or other records), those specified controls shall be implemented.

B. If samples have limited use or storage life, then methods shall be established that preclude using the sample beyond its intended use or storage life.

C. If sample storage is required, then methods shall be established for the control of sample identification that is commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:

1. Maintenance or replacement of markings and identification tags damaged during handling or aging

2. Protection of identification markings subject to excessive deterioration resulting from environmental exposure

3. Updating related documentation.

II.2.5 Archiving Samples

Implementing documents shall specify the representative samples to be archived if the need to archive samples is identified.

II.2.6 Handling, Storage, and Shipping

A. Handling, storage, cleaning, packaging, shipping, and preservation of samples shall be conducted in accordance with established implementing documents or other specified documents.

B. If required for critical, sensitive, perishable, or high-value samples, specific measures for handling, storage, cleaning, packaging, shipping, and preservation shall be identified and used.

C. Measures shall be established for the marking and labeling for packaging, shipping, handling, and storage of samples, as necessary, to adequately identify, maintain, and preserve the sample.

D. Markings and labels shall indicate the presence of special environments or the need for special controls, if necessary.

E. If required for particular samples, special equipment (i.e., containers) and special protective environments (i.e., inert gas and moisture and temperature limits) shall be specified and provided.

F. Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling.

1. Special handling tools and equipment shall be inspected and tested in accordance with implementing documents and at specified time intervals to verify that the tools and equipment are adequately maintained.

2. Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

II.2.7 Disposition of Nonconforming Samples

A. Samples that do not meet requirements specified in work-controlling documents shall be documented, evaluated, identified, and segregated in accordance with Section 15.0.

B. The disposition for nonconforming samples shall be identified and documented and shall be limited to “use-as-is,” “limited use,” or “reject.”

SUPPLEMENT III SCIENTIFIC INVESTIGATION

III.1 GENERAL

A. This supplement establishes requirements for scientific investigations, including data identification, data reduction, and model development and use.

B. Other applicable sections and supplements of the QARD also apply to scientific investigations.

III.2 REQUIREMENTS

III.2.1 Planning Scientific Investigations

A. Scientific investigations shall be planned in accordance with Section 2.0.

B. Planning shall be coordinated with organizations providing input to or using the results of the investigation.

C. Planning shall address provisions for determining the accuracy, precision, and representativeness of results.

III.2.2 Performing Scientific Investigations

A. All documentation resulting from scientific investigation shall be transparent, identify principal lines of investigation considered, and be legible and in a form suitable for reproduction, filing, and retrieval.

B. Scientific investigations shall be performed using scientific notebooks, implementing documents, or a combination of both.

C. Scientific notebooks shall contain the following:

1. Statement of objective and description of work to be performed, or reference to an approved planning document or implementing document that addresses those topics

2. Identification of method(s) and computer software used

3. Identification of any samples or M&TE used

4. Description of the work as it was performed and results obtained, names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries

5. Description of changes made to methods used, as appropriate.

D. Scientific notebooks shall be reviewed by an independent qualified individual to verify there is sufficient detail to:

1. Retrace the investigations and confirm the results, or

2. Repeat the investigation and achieve comparable results, without recourse to the original investigator.

III.2.3 Data Identification

A. Data shall be identified in a manner that facilitates traceability to associated documentation.

B. Data shall be identified in a manner that facilitates traceability to its qualification status.

C. Identification and traceability shall be maintained throughout the lifetime of the data.

III.2.4 Data Review, Adequacy, and Usage

A. Data reduction shall be described to permit independent reproducibility by another qualified individual.

B. Data from scientific investigation activities that are used as direct input to site characterization, and scientific analysis or performance modeling that address safety and waste isolation issues shall be qualified from origin, except as allowed in Paragraph III.2.4B.2. External source data that are not identified as established fact and are used as direct input to scientific analysis or performance modeling must be qualified for its intended use.

1. Data shall be reviewed by individuals other than those who collected or reduced the data to ensure technical correctness.

2. Unqualified data may be used in scientific investigation provided traceability to its status as unqualified data is maintained. Unqualified data that are used as direct input to scientific analysis or performance modeling that address safety and waste isolation issues shall be qualified in accordance with Paragraph III.2.4C at appropriate times during the scientific investigations and before:

a. Relying on the data to support the License Application (e.g., prior to submittal of the application to the NRC),

b. Relying on the item for which the data were used as design input to perform its function, or

c. Relying on the data to resolve safety or waste isolation issues.

C. Unqualified data developed from scientific investigation activities that are used as direct input to site characterization, scientific analysis or performance modeling that address safety and waste isolation issues shall be qualified. External source data that are not identified as established fact and are used as direct input to scientific analyses or performance modeling shall be qualified. One or a combination of the following methods shall be used in performing qualification activities:

1. Determination that the controls under which the data were generated are similar in scope and implementation to the QARD

2. Evaluation of corroborating data – Rationale for selecting one set of data to corroborate another set of data shall be clearly explained and justified

3. Confirmatory testing

4. Peer review in accordance with Section 2.0

5. Technical assessment to independently evaluate data, which includes one or a combination of the following:

   a. Determination that the employed methodology is acceptable

   b. Determination that confidence in the data acquisition or developmental results is warranted

   c. Confirmation that the data have been used in similar applications.

D. The methods in Paragraphs III.2.4C.1, III.2.4C.2, and III.2.4C.3 shall include a review to determine the technical correctness of the data in accordance with established review criteria.

E. The qualification process shall be planned and documented. Documentation shall include:

1. The factors used in arriving at the choice of the qualification method(s)

2. The acceptance criteria used to determine if the data are qualified

3. The rationale for discontinuing any qualification methods abandoned after the initiation of the qualification process

4. The decision as to the qualification of the data.

F. When acquired non-Q data is subsequently identified as necessary to support an activity in which the QARD applies, that data may be used in the Q application provided:

1. Prior review and approval by the responsible OCRWM line organization director and the Director, Office of Quality Assurance, is obtained.

2. Planning for data use is performed in accordance with Subsection III.2.1.

3. The data to be used is identified, controlled, and qualified as described in Subsections III.2.3 and III.2.4.

III.2.5 Technical Report Review

Technical reports shall be reviewed in accordance with the requirements of Subsection 6.2.3.

III.2.6 Model Development and Use

A. Model development and approaches to validation shall be planned, controlled, and documented. Planning for model validation shall identify the validation methods and the validation criteria used. If model validation activities will be completed after documentation of the model (e.g., using new confirmation test data gathered in the field or laboratory), these activities shall be described in the work-planning document.

B. Documentation of models shall be in accordance with Section 17.0, be transparent, and include:

1. Definition of the objective (intended use) of the model.

2. Description of conceptual model and scientific basis, as well as alternatives for the selected conceptual model. Rationale for not selecting alternatives shall also be included.

3. Results of literature searches and other applicable background information.

4. Identification of inputs and their sources.

5. Identification of, and rationale for, assumptions that are made to develop or apply the model, including model idealizations, as well as those assumptions that support the input to the model and impact model results.

6. Discussion of mathematical and numerical methods that are used in the model, including governing equations, formulas, and algorithms, and their scientific and mathematical bases.

7. Identification of any associated software used, computer calculations performed, and basis to permit traceability of inputs and outputs.

8. Discussion of initial and/or boundary conditions.

9. Discussion of model limitations (e.g., data available for model development, valid ranges of model application, spatial and temporal scaling).

10. Discussion of model uncertainties (i.e., conceptual model, mathematical model, process model, abstraction model, system model, parameters) and how they affect the model.

11. Identification of the originator, reviewer, and approver.

C. Computer software used to develop or execute the model shall be qualified in accordance with the requirements of Supplement I.

1. Unqualified software may be used to produce preliminary output that may be used in preliminary technical products, subject to the following controls:

a. Unqualified software used to produce preliminary output shall be identified to SCM for the purpose of tracking the preliminary application of in-process software that is anticipated to be controlled per SCM procedures once it is qualified.

b. Use of all outputs from unqualified software shall be documented and tracked in accordance with the procedure for management of technical product inputs.

c. Outputs from unqualified software shall be appropriately identified as To Be Verified (TBV) or TBV-Temp in accordance with the procedure for management of technical product inputs.

d. When unqualified software has been qualified and baselined, all preliminary data runs shall be rerun using the qualified software for comparison with the preliminary outputs.

i. If outputs are identical, then update the preliminary output with the final output in accordance with the governing technical product procedure.

ii. If outputs are not identical, then supersede the preliminary output with the output from the qualified software in accordance with the governing technical product procedure.

iii. The results of the comparisons and subsequent actions shall be documented within the technical product.

e. Responsible managers, leads, checkers, and quality engineering representatives for technical products shall ensure that all software used within the technical product has been qualified and baselined prior to final approval of the technical product in accordance with the governing technical product procedure.

2. Use of unqualified software under these provisions is strictly limited to use within preliminary technical products in direct support of OCRWM activities related to obtaining a license to construct a repository, including rework in support of the License Application. No other use of these provisions shall be permitted for any other purpose.

D. The intended use of the model and the importance of the model for assessing repository system performance shall determine the appropriate level of confidence for a model (i.e., models of system components most relied upon shall be validated with the highest levels of confidence to the extent practical).

E. Model validation criteria shall address the following:

1. Criteria used to establish the adequacy of the scientific basis for the model shall be consistent with the model application and justified in the model documentation.

2. Criteria used to demonstrate that the model is sufficiently accurate for its intended use. Model documentation shall provide an accounting for uncertainties and variabilities in parameter values and provide the technical basis for parameter ranges, probability distributions, or bounding values used in process, abstraction, and system models used in (or supporting) the post-closure performance assessment.

3. The importance of the model for assessing repository system performance shall be defined.

4. The relative level of confidence for the model shall be described.

5. The supporting information needed to substantiate validation shall be defined.

F. The usual progression of a model is from conceptual model to mathematical model to process model to abstraction model to system model. A conceptual model shall be validated when its implementation as a mathematical, process, abstraction, or system-level model is validated. Technical review through publication in a refereed professional journal or review by an external agency

may be used to corroborate model validation when used in conjunction with one or more of the following:

1. Corroboration of model results with data acquired from field experiments, analogue studies, laboratory experiments, or subsequent relevant observations (e.g., refereed journals or literature). Data used to develop and calibrate a model shall not be used to validate a model.

2. Peer review (Subsection 2.2.8) or independent technical review (Subsection 6.2.3).

3. Performance confirmation studies using validation test model predictions prior to comparison with field or laboratory data.

4. Comparison of model results with other model results obtained from the implementation of an alternative model.

SUPPLEMENT IV FIELD SURVEYING

IV.1 GENERAL

A. This supplement establishes requirements for field surveying. Examples of work that have the potential to require field surveying services for location determination include site characterization, explorations, and installations.

B. Other applicable sections of the QARD also apply to field surveying activities.

IV.2 REQUIREMENTS

IV.2.1 Field Survey System

A. A permanent system of horizontal and vertical controls shall be established and maintained.

B. This system shall be used in accordance with implementing documents to obtain the accurate location and relocation of designated features, including locations of sample or data collection.

IV.2.2 Field Survey Documentation

Pertinent survey documents shall be identified, maintained, and verified for completeness as the work progresses.

SUPPLEMENT V CONTROL OF THE ELECTRONIC MANAGEMENT OF INFORMATION

V.1 GENERAL

This supplement applies to the processes and controls for the management of information that either exists or is used in an electronic format. This includes electronically formatted information used in design input, developed as design output, or developed as an output of scientific investigation or performance assessment modeling and analysis.

Development, acquisition, and modification of software, including database applications or software that performs functions of analysis or calculation, shall be controlled in accordance with Supplement I. The acquisition, development, and use of information shall be controlled by the requirements of Section 3.0 or Supplement III.

V.2 REQUIREMENTS

V.2.1 Control of the Electronic Management of Information

Controls shall be established to ensure that:

A. Information is suitably protected from damage and destruction during its prescribed lifetime and is readily retrievable.

B. A description is prepared of how information will be stored with respect to media, conditions, location, retention time, security, and access.

C. Storage and transfer media are properly identified as to source, physical and logical format, and relevant date (i.e., date written).

D. The completeness and accuracy of the information input and any subsequent changes to the information are maintained.

E. The security and integrity of the information is maintained.

F. Transfers of information are error free or (where applicable) within a defined permissible error rate, to ensure that no information is lost in transfer and the input is recoverable from the output. Examples of information transfers include copying raw information from a notebook to a computerized form, copying from computer tape to disk, writing to a compact disk, etc.

APPENDIX A WASTE CUSTODIAN INTERFACE

A.1 GENERAL

The term waste custodian refers to an organizational entity that is in possession of high-level radioactive waste (HLW) or spent nuclear fuel (SNF) planned for disposition at the geologic repository. This includes commercial nuclear utilities, U.S. Department of Energy (DOE) Office of Environmental Management (EM) sites, and the Naval Nuclear Propulsion Program (NNPP).

A.1.1 Commercial Nuclear Utilities

A. Because the characteristics of commercial SNF are well known and readily available, the OCRWM does not rely on specific information submittals from commercial nuclear utilities to perform activities subject to the QARD. In addition, commercial nuclear utilities are already required to work to U.S. Nuclear Regulatory Commission (NRC) approved 10 CFR 50, Appendix B, Quality Assurance (QA) programs.

B. In the future, the OCRWM intends to rely on information provided by commercial nuclear utilities to support waste acceptance activities. The OCRWM anticipates that commercial nuclear utilities will be able to support waste acceptance activities with information gathered under their NRC-approved 10 CFR 50, Appendix B, QA programs. If necessary, the interface between commercial nuclear utilities and the OCRWM will be addressed in greater detail when the QARD is revised to address waste acceptance activities (i.e., prior to issuance of license to receive and possess HLW and SNF).

A.1.2. Federal Waste Custodians

A. The OCRWM interfaces directly with federal waste custodians and their principal contractors to obtain information and/or data to support activities subject to the QARD (e.g., scientific document development, design, etc.). The OCRWM has developed the requirements described in this appendix to ensure that appropriate QA controls are implemented by federal waste custodians and their principal contractors.

B. Federal waste custodians and their principal contractors perform activities to ensure and document that their HLW and SNF will meet OCRWM waste acceptance criteria. In some cases federal waste custodians and/or their principal contractors also design and fabricate items that will be considered important to safety or waste isolation. Although these activities do not affect DOE's ability to comply with 10 CFR 63 at this time, they will in the future (i.e., during and after waste acceptance). Federal waste custodians and/or their principal contractors work to QA programs that meet the applicable requirements of either an NRC-approved 10 CFR 50, Appendix B, QA program, or a 10 CFR 63.142 QA program. The applicable requirements of these QA programs are flowed

down to their principal contractors by the federal waste custodians. The controls identified in this appendix also apply to work performed to support future HLW and SNF acceptance.

C. Interfaces between the OCRWM and federal waste custodians are defined in formal agreement documents (i.e., Memoranda of Agreement or Understanding). Agreement documents also identify requirements that the federal waste custodians will need to meet for OCRWM to use their work products (e.g., License Application input and designed or fabricated items that will be considered important to safety or waste isolation) and accept their HLW or SNF for disposal. The OCRWM will verify the implementation of these requirements through audits, surveillance, reviews, or observations prior to accepting their work products or accepting HLW or SNF.

D. Federal waste custodians normally contract some or all of the work addressed in this appendix to their principal contractors. Agreement documents will be executed between the OCRWM and senior management of the office that encompasses the federal waste custodians. Federal waste custodians are responsible for passing the appropriate provisions of the agreement document down to their principal contractors.

E. Agreement documents are not procurement documents; however, for the purpose of providing the appropriate level of control over OCRWM and federal waste custodian interface, the applicable requirements of 10 CFR 63.142 will be applied to the development, control, and revision of agreement documents.

A2. SPECIFIC DISCUSSION OF OCRWM INTERFACE WITH FEDERAL WASTE CUSTODIANS

A.2.1 Interface with the Office of Environmental Management

A. The OCRWM's agreement with EM identifies the technical and quality requirements that apply to work associated with HLW and SNF and identifies the requirements of 10 CFR 63.142 that are applicable to EM federal waste custodians' principal contractors.

B. The agreement also describes the oversight of EM federal waste custodians and their principal contractors performing work covered in the agreement. EM and the OCRWM jointly perform audits of EM federal waste custodians and their principal contractors. Audit teams include at least one OCRWM OQA team member. Audits are performed in accordance with approved OCRWM implementing documents.

C. The EM National Spent Nuclear Fuel Program provides the OCRWM with information related to DOE SNF, so it is treated as a waste custodian even though it does not actually possess SNF or HLW.

A.2.2 Interface with the Naval Nuclear Propulsion Program

A. The NNPP is a joint U.S. Department of the Navy/DOE organization and, as promulgated under Executive Order 12344 (42 U.S.C. Section 7158 and 50 U.S.C. Section 2406), is responsible for all matters pertaining to naval nuclear propulsion. Within DOE, the NNPP is known as the Office of Naval Reactors and is considered a federal waste custodian. The NNPP's QA program has been a key contributor to the success of the NNPP throughout its over 50-year history. The QA program validates that the fundamental quality necessary for a successful naval nuclear program is built into all components and processes.

B. The NNPP QA program applies to all aspects of design, operation, construction, and maintenance of naval nuclear propulsion plants, including work to support emplacement of naval SNF in the geologic repository. NNPP QA requirements embody the 18 quality criteria of 10 CFR 63.142. An agreement document defines the interface between the NNPP and OCRWM for the purpose of OCRWM acceptance of naval SNF for disposal. This agreement specifies that the NNPP QA program shall be defined and administered solely by the NNPP in accordance with its statutory obligations and that the NNPP is responsible for conducting all oversight of NNPP activities related to acceptance of naval SNF. Under the agreement, OCRWM is responsible for reviewing NNPP QA practices regarding naval SNF and for determination of the sufficiency of these practices for disposal at the repository. The agreement provides for OCRWM observations of NNPP QA practices and periodic discussion and updates regarding these practices so that the OCRWM can fulfill its responsibilities under the agreement.

C. Interactions between the OCRWM and NNPP regarding the NNPP QA program started in the mid-1990s and led to a comprehensive OQA review and acceptance of the NNPP QA program as it applies to disposal of naval SNF in the geologic repository.

D. The OCRWM monitors the NNPP QA program to ensure it remains acceptable to the OCRWM. Monitoring activities include periodic observations of NNPP QA program oversight of various NNPP QA program elements and contractor QA program activities, as well as annual reviews of NNPP QA audits, surveillance, inspection reports, implementing document revisions, compliance matrices, and organizational changes.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
A	Regulatory Guide 1.28, Revision 3, (8/1985), "Quality Assurance Program Requirements (Design and Construction)," which endorses ANSI/ASME NQA-1-1983 and ANSI/ASME NQA-1a-1983 Addenda (NQA-1)	ANSI/ASME NQA-1-1983 with ANSI/ASME NQA-1a-1983 Addenda, as supplemented or modified by the regulatory positions cited in section C of Regulatory Guide 1.28	The OCRWM commits to the requirements and recommendations of the Regulatory Positions of this Regulatory Guide and the basic, supplementary requirements, and Appendix 2A-1 and Appendix 2A-3 of the endorsed standard as supplemented or modified by the Regulatory Positions, with the following exceptions:
			1. In lieu of implementing the requirements and recommendations of Regulatory Guide position C.2, Quality Assurance Records, the OCRWM will retain QA records in accordance with the retention and disposition instructions contained in a records retention schedule maintained by the OCRWM. The retention periods delineated in this records retention schedule shall meet or exceed the retention requirements delineated in Regulatory Guide 1.28, Revision 3, Table 1.
			2. General comment: ANSI/ASME NQA-1 refers to terms such as refueling, operations, inservice inspection, decommissioning, etc. These are examples of activities that will occur during the period of time that DOE has received a license to receive and possess Spent Nuclear Fuel and High Level Waste. At the appropriate time the QARD will be revised to address these activities.
			3. In lieu of ANSI/ASME NQA-1, Supplement S-1, Terms and Definitions, the QARD will maintain a glossary of terms and definitions independent of this standard. The terms and definitions in the QARD glossary are consistent with Supplement S-1.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
			4. ANSI/ASME NQA-1, Supplement 2S-2, requires implementing American Society of Nondestructive Testing *Recommended Practice No. SNT –TC-1A* (6/1975) and applicable supplements to Nondestructive Examination (NDE) personnel. In lieu of this requirement the ORD will implement the requirements of SNT-TC-1A (6/1980) edition with one additional exception. In lieu of the three (3) year re-certification interval specified in SNT-TC-1A (6/1980) edition, Level III NDE personnel may be re-certified on a five year interval. The qualification and certification will include a performance demonstration as part of the practical examination.
			5. ANSI/ASME NQA-1, Supplement 2S-3, Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel, requires that, Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. In lieu of this requirement the QARD will require as an alternative the following: The lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited.
			6. INTENTIONALLY BLANK
			7. ANSI/ASME NQA-1-1983, Supplement 7S-1, Supplementary Requirements for Control of Purchased Items and Services, provides amplified requirements for the control of purchased items and services. As an alternative to the imposition of all otherwise applicable requirements for the procurement of analytical services in support of scientific investigations, the OCRWM will implement the purchaser related requirements described in QARD, Subsection 7.2.12B.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
			8. ANSI/ASME NQA-1, Supplement 6S-1, Supplementary Requirements for Document Control, Section 3.1, Major Changes, requires that changes to documents, other than those defined as minor in 3.2 below, are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The OCRWM will implement the following alternative: The OCRWM will limit the scope of the "Minor Changes" category to the inconsequential editorial corrections described in QARD, Subsection 6.2.8. Controlled document changes outside this scope will be treated as "Major Changes" and reviewed and approved as described in QARD, Subsection 6.2.6.
			9. ANSI/ASME NQA-1, Supplement 7S-1, Supplementary Requirements for Control of Purchased Items and Services, Section 10, Commercial Grade Items. NUREG-1804, Acceptance Criteria 7 takes exception to the provisions of ANSI/ASME NQA-1 regarding commercial grade item dedication. Consistent with the NRC position stated in NUREG-1804, the OCRWM will not conduct a commercial grade program in accordance with the provisions in ANSI/ASME NQA-1. The OCRWM commercial grade item dedication program is based on the guidance of NUREG-1804, acceptance criteria AC-7(8) and the applicable requirements of 10 CFR 21.
			10. ANSI/ASME NQA-1, Supplement 17S-1, Supplementary Requirements for Quality Assurance Records, Sections 2.7 and 2.8, Classification, addresses criteria and requirements for the classification (lifetime and nonpermanent) and retention of Quality Assurance records,

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
			respectively. Regulatory Guide 1.28, Regulatory Position C.2, *Quality Assurance Records* in conjunction with Table 1, Retention Times for Lifetime and Nonpermanent Records, and NQA-1-1983, Supplement 17S-1, *Supplementary Requirements for Quality Assurance Records*, Sections 2.7, Classification, and 2.8, Retention of Records, prescribe requirements for the development of a number of classes of QA records and rules and guidance for specifying the minimum retention time to be applied to each class of record. The objective of these directions is to ensure the availability and retrievability of each class of QA records during the specified retention period and to provide relief from the necessity to retain the specified records beyond the required retention period. As an alternative to the above, all QA records will be treated as one class of record without further classification such as Lifetime, Nonpermanent, Programmatic Nonpermanent, or Product Nonpermanent. Retention of all QA records is specified in the comprehensive schedule required by 36 CFR, Chapter XII, Subchapter B, Records Management, Part 1220, Federal Records, General. That schedule is titled "OCRWM Program Records Retention Schedule (OPRRS)," which will be superseded by the "YMP Records Retention Schedule" in the near future. This schedule now requires and will continue to require in the future that all QA records be retained **until the end of the operating period**. At that time, the records will be reappraised for utility during the postclosure period. If retention during the postclosure period is indicated, disposition instructions will be revised at that time. If retention during the postclosure period is not required, the records will be destroyed.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
			11. ANSI/ASME NQA-1, Supplement 17S-1, Supplementary Requirements for Quality Assurance Records, addresses the requirements and recommendations for the storage of records that are determined to be QA records. This supplement does not include a provision for the temporary storage of QA records. The QARD includes the following provision for temporary storage of QA records: a. QA records shall be temporarily stored in a container or facility with a fire rating of one hour, or dual storage shall be provided. b. For single storage, containers or facilities shall bear an Underwriters' Laboratories label (or equivalent) certifying 1-hour fire protection or be certified by a person competent in the technical field of fire protection. c. The period of time allowed for records to be in temporary storage will be specified in appropriate procedures.
			12. ANSI/ASME NQA-1, Supplement 17S-1, Supplementary Requirements for Quality Assurance Records, Section 4.4.2, Alternate Single Facility, since OCRWM will not be using the alternate facility, the QARD is silent on this aspect of ANSI/ASME NQA-1.
			13. ANSI/ASME NQA-1, Supplement 17S-1, Supplementary Requirements for Quality Assurance Records, Section 5, Retrieval, the OCRWM records retrieval system is not configured in such a manner as to provide retrieval times based on the type of record.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
			14. ANSI/ASME NQA-1, Supplement 17S-1, Supplementary Requirements for Quality Assurance Records, Section 6, 3rd paragraph, specifies certain conditions and events prior to which supplier's nonpermanent records shall not be disposed of. As an alternative to directing the disposal of any QA records by a supplier, the supplier shall be required to submit all QA records generated in the course of a procurement action to the OCRWM. These QA records shall thereafter be retained in accordance with the direction of the OPRRS.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
			15. ANSI/ASME NQA-1, Supplement 18S-1, Supplementary Requirements for Audits, Section 3.3, 2nd sentence requires audit response evaluation to be a function of the individual appointed to lead the (audit) team. As an alternative, conditions identified during performance of an audit, which require the attention of the audited organization, are processed in accordance with the requirements of QARD Section 16.0. Thereafter, all actions related to those corrective actions, e.g., responses, evaluation of responses, corrective action planning, performance, and verification, are managed through the implementation of QARD Section 16.0.
			16. ANSI/ASME NQA-1, Supplement 18S-1, Supplementary Requirements for Audits, Section 6, Response, requires that the "Management of the audited organization… notify… in writing of the action taken or planned." In the case of internal audits, it is OCRWM's position that such a response is not necessary. The results of internal audits are placed into the electronic Corrective Action system. The results of the investigation, including determination of cause, as appropriate, reviews, approvals, corrective actions, and schedules are available to the auditing organization. Therefore, there is not a necessity for a written response.
			17. ANSI/ASME NQA-1, Supplement 18S-1, Supplementary Requirements for Audits, Section 6, requires measures to prevent recurrence to be identified for adverse audit findings. In lieu of this requirement, OCRWM will process adverse audit findings in accordance with QARD Section 16.0. QARD Section 16.0 requires responsible management to take corrective action to prevent recurrence for significant conditions adverse to quality.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
B	Regulatory Guide 1.8, Revision 3 (5/2000), "Qualification and Training of Personnel for Nuclear Power Plants"	This regulatory guide endorses ANSI/ANS-3.1-1993, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants," with certain additions and exceptions that are listed in the Regulatory Position of this guide.	The OCRWM commits to the requirements and recommendations for the selection, qualification, and training of personnel, subject to the additions, exceptions, and clarifications provided in Section C, Regulatory Position, of the Regulatory Guide, with the following exceptions: For the purpose of the Construction Authorization, the commitment is limited to the following Regulatory Position; C.2.1.1. These include Paragraph 4.3.7 of the endorsed standard. In addition, for the purpose of the Construction Authorization, NUREG-1804, Section 2.5.1, Acceptance Criteria 1, item 7, requests that the qualification requirements for the "QA Manager" be equivalent to those provided in the ANSI/ANS Standard as endorsed by the Regulatory Guide.
C	NRC Information Notice 86-21, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," (3/31/1986), including Supplement 1 (12/04/1986), and Supplement 2 (4/16/1991)		The ORD will recognize ASME accreditation of suppliers as stated in the NRC Information Notice.
D	NUREG-1297, "Peer Review for High-Level Nuclear Waste Repositories" (1988)		The OCRWM commits to the requirements and recommendations of Section III, Definitions, and Section IV, Staff Position, of this NUREG-1297.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
E	NUREG-1298, "Qualification of Existing Data for High-Level Nuclear Waste Repositories" (1988)		The OCRWM commits to the requirements and recommendations of Section IV, Staff Positions of NUREG-1298, with the following alternatives: NOTE: If the requirements of NUREG-1298 are in conflict with the requirements of 10 CFR 63, the requirements of 10 CFR 63 shall take precedence. E.1 In addition to the four methods listed in Staff Position 2, OCRWM uses a fifth method, Technical Assessment, which includes one or a combination of the following: – Determination that the employed methodology is acceptable; – Determination that confidence in the data acquisition or developmental results is warranted; or – Confirmation that the data have been used in similar applications. Additionally, the QA program that is discussed in Staff Position IV.1 is understood to mean 10 CFR 60, Subpart G, or 10 CFR 63.142, depending at the point in time when the data was required to be qualified.
			E.2 In those instances after implementation of the 10 CFR 60/63 QA program, when the development of required data by any external source cannot be obtained through the imposition of otherwise applicable requirements of the QARD Section 7.0, the OCRWM will permit such development as a routine commercial procurement activity upon prior approval by the responsible OCRWM line organization director and the Director, Office of Quality Assurance. Data developed in this manner shall be subjected to the data qualification process applicable to qualification of unqualified data.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
			E.3 In those instances after the implementation of the 10 CFR 60/63 QA Program, when required data is shown to already exist in the form of the product of a non-Q acquisition, the OCRWM will permit use of that data in an activity to which the QA program applies upon prior approval by the responsible OCRWM line organization director and the Director, Office of Quality Assurance. Such data shall be subjected to the data qualification process applicable to the qualification of unqualified data.
F	NUREG-1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program" (1996)		The OCRWM commits to the requirements and recommendations of Section 3, Branch Technical Position, and Appendix A, Glossary, of this NUREG with the following exception: Step 7 of NUREG-1563 recommends documenting the rationale for any revisions to elicited evaluations after the experts receive feedback on their initial evaluations. OCRWM does not require documentation of the rationale for revisions to an expert's initial assessment in the expert elicitation report.
G	NUREG-1636, "Regulatory Perspectives on Model Validation in High-Level Radiation Waste Management Programs: A Joint NRC/SKI White Paper" (1999)		The OCRWM commits to the requirements and recommendations in Section 3, Model Validation Approach from a Regulatory Perspective of NUREG-1636, to the extent presented in QARD Supplement III, Scientific Investigation, Section III.2.6.
H		ASME NQA-1 (2000), Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications."	The OCRWM commits to the requirements of ASME NQA-1 (2000) Subpart 2.7 with the following exception: All references to other requirements of Part I in ASME NQA-1 (2000), Subpart 2.7, are understood to be referring to the appropriate criteria of ANSI/ASME NQA-1-1983 with ANSI/ASME NQA-1a-1983 addenda, as supplemented or modified by regulatory positions cited in Section C of Regulatory Guide 1.28.

Table 1. Regulatory/Commitment Document Positions

Item	U.S. NRC Document	National/Industry Standard	OCRWM Position
I	Regulatory issue Summary 2000-18, *Guidance on Managing Quality Assurance Records in Electronic Media*		The OCRWM will be using an electronic records system for Quality Assurance records. As such, OCRWM commits to the use of the NRC guidance contained within the RIS.
J	Electric Power Research Institute (EPRI) *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications* (NCIG-07), EPRI NP-5652 (6/88), as endorsed and modified by U.S. Nuclear Regulatory Commission Generic Letters 89-02, *Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products* (3/89) and 91-05, *Licensee Commercial-Grade Procurement and Dedication Programs* (4/91)	Electric Power Research Institute (EPRI) *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications* (NCIG-07), EPRI NP-5652 (6/88), as endorsed and modified by U.S. Nuclear Regulatory Commission Generic Letters 89-02, *Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products* (3/89) and 91-05, *Licensee Commercial-Grade Procurement and Dedication Programs* (4/91).	If OCRWM, OCRWM contractors, or suppliers implement a commercial grade item dedication process as defined in 10 CFR 21.3, the implementing processes shall be developed with the guidance contained in Electric Power Research Institute (EPRI) *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications* (NCIG-07), EPRI NP-5652 (6/88), as endorsed and modified by U.S. Nuclear Regulatory Commission Generic Letters 89-02, *Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products* (3/89) and 91-05, *Licensee Commercial-Grade Procurement and Dedication Programs* (4/91).
K		American Society for Nondestructive Testing (ASNT) *Recommended Practice No. SNT-TC-1A*, June 1980 Edition	The OCRWM commits to the requirements of SNT-TC-1A (6/1980) edition with one additional exception. In lieu of the three (3) year re-certification interval specified in SNT-TC-1A (6/1980) edition, Level III NDE personnel may be re-certified on a five year interval. The qualification and certification will include a performance demonstration as part of the practical examination.

GLOSSARY

***Acceptance (Document*)**–The documented determination by the receiving organization that work is suitable for the intended purpose.

Acceptance Testing (Software)–The process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment. (NQA-1-2000, Subpart 2.7, Section 102)

Application (Software)–Includes software designed to fulfill the specific needs of a user and software that are written where the user prescribes one or more instructions to generate data, manipulate data, or perform calculations. (IEEE Std. 610.12-1990)

Approval–The documented determination by a responsible organization that work is suitable for the intended purpose and shall be used as required.

Audit–A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance. (NQA-1-1983, Supplement S-1)

Audit Team Leader–A lead auditor who is assigned to direct the efforts of an audit team.

Auditor–An individual who is qualified to perform assigned portions of an audit.

Baseline Element (Software)–An individual software component (e.g., requirements document, design document, source code, etc.) that is under configuration management control.

Basic Component–When applied to facilities or activities licensed pursuant to 10 CFR 63, a structure, system, or component or part thereof that affects their safety or waste isolation function, that is directly procured by the licensee of a facility or activity subject to the regulations in 10 CFR 21 and in which a defect or failure to comply with any applicable regulation in Title 10, Chapter I, order, or license issued by the U.S. Nuclear Regulatory Commission could create a substantial safety hazard. The term includes activities important to safety or important to waste isolation such as design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others. (10 CFR 21.3)

Certificate of Conformance–A document signed by an authorized individual certifying the degree to which items or services meet specified requirements. (NQA-1-1983, Supplement S-1)

Certification–The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements. (NQA-1-1983, Supplement S-1)

Characteristic–A property or attribute of an item, process, or service that is distinct, describable, and measurable. (NQA-1-1983, Supplement S-1)

Code Data Report (ASME Section III)–A report required by the ASME Boiler and Pressure Vessel Code, such as Form N-1, Certificate Holders' Data Report For Nuclear Vessels, or Form N-3, Owners' Data Report for Nuclear Power Plant Components.

Commercial Grade Item–An item that is not subject to design or specification requirements that are unique to nuclear facilities or activities, is used in applications other than nuclear facilities or activities, and is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturers published product description (e.g., catalog). (10 CFR 21.3)

Commercial Grade Survey–Activities conducted by the purchaser or its agent to verify that a principal contractor/supplier of commercial grade items controls through quality activities, the critical characteristics of specifically designated commercial grade items, as a method to accept those items for important to safety or important to waste isolation use. (EPRI NP-5652, 6/88-Modified)

Commercial Off-The-Shelf Software–Software items that can be purchased, ready-made, from a principal contractor's/supplier's/retailer's store shelf or manufacturer's virtual store shelf (e.g., through a catalog or from a price list) on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog or other published specification).

Computer Program–A combination of computer instructions and data definitions that enable computer hardware to perform computational or control functions. Computer programs covered by this document are those used in quality affecting activities. (NQA-1-2000, Part I, Section 400, Modified)

Conceptual Model–A set of qualitative assumptions used to describe a system or subsystem for a given purpose. Assumptions for the model are compatible with one another and fit the existing data within the context of the given purpose of the model. (NUREG-1804, Section 3, Glossary)

Condition Adverse to Quality–An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. (NQA-1-1983, Supplement S-1)

Configuration Item (Software)–A collection of hardware or software elements treated as a unit for the purpose of configuration control. (NQA-1-2000, Subpart 2.7, Section 102)

Configuration Management (Software)–The process of identifying and defining configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests. (NQA-1-2000, Subpart 2.7, Section 102)

Confirmatory Testing–Testing conducted under a 10 CFR 60, Subpart G, or 10 CFR 63, Subpart G, QA program that investigates the properties of interest (e.g., physical, chemical, geologic, or mechanical) of an unqualified database.

Consumables–Items that in the process of being used are consumed (e.g., weld rods).

Control Point (Software)–A point in the software life cycle at which specified agreements or controls (typically a test or review) are applied to the software configuration items being developed (e.g., an approved baseline or release of a specified document or computer program). (NQA-1-2000, Subpart 2.7, Section 102)

Controlled Document–A document that is prepared, reviewed, and approved in accordance with established implementing documents; subject to controlled distribution; and subject to a defined change process.

Corrective Action–Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition. (NQA-1-1983, Supplement S-1)

Corroborating Data–Unqualified or qualified data used to support or substantiate other unqualified data. (NUREG-1298 [2/88]-Modified)

Critical Characteristics–The important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function, or reasonable expectation that the item will perform its intended waste isolation function. (NUREG-1804, AC-7[8][b])

Data–Information measured or derived from scientific investigation activities both in the field and the laboratory. Parameters that have been derived from raw data are sometimes themselves considered to be data.

Database–A collection of previously distinct data (not created by the database) that have been logically organized to facilitate data access.

Data Reduction–Processes that change the form of expression, quantity of data or values, or the number of data items.

Dedicating Entity–The organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the U.S. Department of Energy itself. The dedicating entity pursuant to 10 CFR 21.21(c) is responsible for identifying and evaluating deviations, reporting defects and failures to comply

for the dedicated item, and maintaining auditable records of the dedication process. (10 CFR 21.3)

Dedication–An acceptance process undertaken to provide (i) reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function or (ii) reasonable expectation that the item will perform its intended waste isolation function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR 63, Subpart G, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by a purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following:

(1) Commercial grade surveys
(2) Product inspections or witnessing at hold points at the manufacturer's facilities, and
(3) Analyses of historical records for acceptable performance.

In all cases, the dedication process shall be conducted in accordance with the applicable requirements of 10 CFR 63, Subpart G. Final dedication of an item occurs after receipt inspection and final acceptance by the U.S. Department of Energy or its contractor, when the item is designated for use as a basic component. (10 CFR 21.3)

Defect–

(1) A deviation in a basic component delivered to a purchaser for use in a facility or activity subject to the regulation in 10 CFR 21 if, on the basis of an evaluation, the deviation could create a substantial safety hazard; or

(2) The installation, use, or operation of a basic component containing a defect; or

(3) A deviation in a portion of a facility subject to the Construction Authorization or licensing requirements of 10 CFR 63, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to part 63 of this chapter. (10 CFR 21.3)

Design–The term "design" includes specifications; drawings; design criteria; design bases; structures, systems, and components performance requirements for preclosure; and natural and engineered barriers of the repository system. It also includes inputs and outputs at each stage of design development (e.g., from conceptual design to final design). Design information and design activities also refer to data collection and analyses and computer software that are used in supporting design development and verification. Design information and activities include general plans and detailed procedures for data collection and analyses and related information such as test and analyses results. Data analyses include the initial

step, data reduction, as well as broad system analyses (i.e., performance assessments) that integrate other data and analyses for individual parameters. (NUREG 1804, AC-3 [2])

Design Bases–Information that identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be constraints derived from generally accepted "state-of-the-art" practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under which the structure, system, or component must meet its functional goals.

The values for controlling parameters for external events include:

(1) Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved, and

(2) Estimates of severe external human-induced events to be used for deriving design bases that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event. (10 CFR 63.2)

Design Change–Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto. (NQA-1-1983, Supplement S-1)

Design Documents–Include, but are not limited to, specifications, calculations, associated computer software, system descriptions, and drawings, including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. (NUREG-1804, AC-3[13][c])

Design Input–Those criteria, parameters, bases, or other design requirements upon which detailed final design is based. (NQA-1-1983, Supplement S-1)

Design Output–Documents, such as drawings, specifications, and other documents defining technical requirements of structures, systems, and components. (NQA-1-1983, Supplement S-1)

Design Process–Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents. (NQA-1-1983, Supplement S-1)

Design Review–A critical review to provide assurance that the final design is correct and satisfactory. (NQA-1-1983, Supplement 3S-1, Paragraph 4.2.1)

Deviation–A departure from specified requirements. (NQA-1-1983, Supplement S-1)

Document Control–The process for controlling documents that provides for adequacy review, approval for release by authorized personnel, and distribution for use at the prescribed work locations. (10 CFR 63.142[g])

Effective Date–The date after approval that the document is required to be fully implemented.

Embedded Software–Software that is a part of a larger system and performs some of the functions of that system, such as keypad controls or function and control capabilities. (IEEE Std. 610.12-1990, Modified)

Error (Software)–A condition deviating from an established baseline, including deviations from the current approved computer program and its baseline requirements. (NQA-1-2000, Subpart 2.7, Section 102)

Established Fact–Information accepted by the scientific and engineering community as established fact (e.g., engineering handbooks, density tables, gravitational laws, etc.).

Event Sequence–A series of actions and/or occurrences within the natural and engineered components of a geologic repository operations area that could potentially lead to exposure of individuals to radiation. An event sequence includes one or more initiating events and associated combinations of repository system component failures, including those produced by an action or inaction of operating personnel. Those event sequences that are expected to occur one or more times before permanent closure of the geologic repository operations area are referred to as Category 1 event sequences. Other event sequences that have at least 1 chance in 10,000 of occurring before permanent closure are referred to as Category 2 event sequences. (10 CFR 63.2)

Expedited Change–An abbreviated method of revising a document at the work location where the document is used, when the normal change process would cause unnecessary delays. The management responsible for the work makes the expedited change.

Field Surveying–The process of determining the boundaries, area, elevation, and location of land, structures, reference points, or other designated features either on, above, or below the earth surface relative to a permanent system of horizontal and vertical controls.

Hold Point–A step in a document that requires witnessing or inspection by the requesting individual or organization and beyond which work shall not proceed without the written consent of the requesting individual or organization. (NQA-1-1983, Supplement 10S-1, Paragraph 3)

Implementation (Software)–The process of translating the software design into a computer program. (IEEE Std. 610.12-1990)

Important to Safety–With reference to structures, systems, and components, means those engineered features of the geologic repository operations area whose function is:

(1) To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of 10 CFR 63.111(b)(1) for Category 1 event sequences; or

(2) To prevent or mitigate Category 2 event sequences that could result in radiological exposures exceeding the values specified at 10 CFR 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site. (10 CFR 63.2)

Important to Waste Isolation–With reference to design of the engineered barrier system and characterization of natural barriers, means those engineered and natural barriers whose function is to provide reasonable expectation that high-level waste can be disposed of without exceeding the requirements of 10 CFR 63.113(b) and (c). (10 CFR 63.2)

Indoctrination–A method of training designed to familiarize personnel in fundamental criteria, program elements, responsibilities, and authority applicable to assigned tasks. (NQA-1-1989, Supplement 2S-4, Paragraph 3)

Information–A representation of data, facts, concepts, or instructions in a manner suitable for communication, interpretation, or processing by individuals or by automatic means.

Inspection–Examination or measurement to verify whether an item or activity conforms to specified requirements. (NQA-1-1983, Section II, Basic Requirement 10)

Item–An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit. (NQA-1-1983, Supplement S-1)

Lead Auditor–An individual who is certified to organize, perform, and direct an audit; report audit results; and evaluate related corrective actions.

Limited Use–A disposition permitted for a nonconforming sample when it can be established that a sample has potential value to the project even though the sample has been determined to be nonconforming in respect to its original obtained condition. For example, samples contaminated by water may still hold value for rock mechanic studies, but hold no value for water infiltration investigations. Conditions for Limited Use will be established and set forth in the disposition of the nonconforming sample.

Management Assessment–An OCRWM QA program verification that is conducted by management above or outside the OCRWM QA organization and that evaluates the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the OCRWM QA program.

Measuring and Test Equipment–Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements. (NQA-1-1983, Supplement S-1)

Model–A depiction of a system, phenomenon, or process including any hypotheses required to describe the system or explain the phenomenon or process. (NUREG-1804, Section 3, Glossary)

Model, Abstracted–A model that reproduces, or bounds, the essential elements of a more detailed process model and captures uncertainty and variability in what is often, but not always, a simplified or idealized form. (NUREG-1804, Section 3, Glossary)

Model, Conceptual–A set of qualitative assumptions used to describe a system or subsystem for a given purpose. Assumptions for the model are compatible with one another and fit the existing data within the context of the given purpose of the model. (NUREG-1804, Section 3, Glossary)

Model, Mathematical–A mathematical description of a conceptual model. (NUREG-1804, Section 3, Glossary)

Model, Process–A depiction or representation of a process, along with any hypotheses required to describe or to explain the process. (NUREG-1804, Section 3, Glossary)

Model, System–A collection of interrelated mathematical models that represents the overall geologic repository or overall component subsystem of the geologic repository.

Model Validation–A process used to establish confidence that a mathematical model and its underlying conceptual model adequately represent with sufficient accuracy the phenomenon, process, or system in question.

Nonconformance–A deficiency in characteristic, documentation, or procedure that renders the quality of an item, sample, or activity unacceptable or indeterminate. (NQA-1-1983, Supplement S-1)

Objective Evidence–Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or test which can be verified. (NQA-1-1983, Supplement S-1)

Organizational Interface–The relationship between organizations in which one organization prescribes an activity or requirement to, or shares an activity or requirement with, another organization.

Performance Assessment (Total System Performance Assessment)–An analysis that:

(1) Identifies the features, events, processes (except human intrusion), and sequences of events and processes (except human intrusion) that might affect the Yucca Mountain disposal system and their probabilities of occurring during 10,000 years after disposal;

(2) Examines the effects of those features, events, processes, and sequences of events and processes upon the performance of the Yucca Mountain disposal system; and

(3) Estimates of the dose incurred by the reasonably maximally exposed individual, including the associated uncertainties, as a result of releases caused by all significant features, events, processes, and sequences of events and processes, weighted by their probability of occurrence. (10 CFR 63.2)

Performance Confirmation–The program of tests, experiments, and analyses that is conducted to evaluate the adequacy of the information used to demonstrate compliance with the performance objectives in 10 CFR 63, Subpart E. (10 CFR 63.2)

Personnel Qualification–See Qualification (Personnel).

Preclosure Safety Analysis–A systematic examination of the site; the design; and the potential hazards, initiating events, and event sequences and their consequences (e.g., radiological exposure to workers and the public). The analysis identifies structures, systems, and components important to safety. (10 CFR 63.2)

Principal Contractors–Organizations that provide items or services in accordance with an appropriate contractual document and that perform the functions of Management and Operating contractor, Management and Integration contractor, Construction contractor or Lead Laboratory.

Process–A series of actions that achieves an end result or accomplishes work.

Procurement Document–Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase. (NQA-1-1983, Supplement S-1)

Purchaser–The organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents. (NQA-1-1983, Supplement S-1)

Qualification (Personnel)–The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function. (NQA-1-1983, Supplement S-1)

Qualification of Data–A formal process that is intended to provide a desired level of confidence that data are suitable for their intended use.

Qualification Testing–A test that is intended to provide a desired level of confidence that an item meets specified criteria.

Qualified Data–Data collected under an approved QA program that meets the requirements of 10 CFR 63.142 (or previously implemented 10 CFR 60 QA program) (i.e., qualified from origin) or unqualified data that have undergone the qualification process. (NUREG-1298, 2/88)

Quality Assurance (QA)–All those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, and components important to safety, the design and characterization of engineered and natural barriers important to waste isolation, and activities related thereto will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, system, or component that provide a means to control the quality of the material, structure, system, or component to predetermined requirements. (10 CFR 63.141)

Quality Assurance (QA) Organization–The Office of Quality Assurance organization for activities performed by the OCRWM and reviews of OCRWM owned documents, the Management and Operating contractor (M&O) QA organization for activities performed by the M&O and reviews of M&O owned documents; the Lead Laboratory QA organization for activities performed by the Lead Laboratory and reviews of Lead Laboratory owned documents; and the Office of Quality Assurance organization, the M&O QA organization, and the Lead Laboratory QA organization for the review of documents implemented by the OCRWM, the M&O, and/or the Lead Laboratory jointly.

Quality Assurance (QA) Record–A completed document (or other medium) that furnishes evidence of the quality of items and/or activities affecting quality. (NQA-1-1983, Supplement S-1)

Readiness Review–A systematic assessment of the preparedness of an organization to start or continue a process or project phase.

Regression Testing–Selective retesting of a system or component to verify that modifications have not caused unintended effects and that the system or component still complies with its specified requirements. (IEEE Std. 610.12-1990)

Release (Software)–The formal notification and distribution of approved software.

Remedial Action–The actions taken to correct specifically identified conditions adverse to quality.

Repair–The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement. (NQA-1-1983, Supplement S-1)

Rework–The process by which an item is made to conform to original requirements by completion or correction. (NQA-1-1983, Supplement S-1)

Right of Access–The right of a purchaser or designated representative to enter the premises of a principal contractor/supplier for the purposes of inspection, surveillance, or quality assurance audit. (NQA-1-1983, Supplement S-1)

Root Cause–The identified cause of a condition adverse to quality that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or a similar condition adverse to quality.

Sample (Physical)–A physical part of a whole whose properties are studied to gain information about the whole.

Scientific Investigation–An analysis consisting of an explanation, observation, identification, description, or experimental study either of natural phenomena or of engineered materials that describe the postclosure repository system or its performance.

Scientific Notebook–A record of the methodology and results of scientific investigations that is used when the work involves a high degree of professional judgment or trial and error methods or both.

Service–The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation. (NQA-1-1983, Supplement S-1)

Significant Condition Adverse to Quality–A condition adverse to quality that, if uncorrected, could have a serious effect on safety, operability, or the ability to isolate waste. Significant conditions adverse to quality include, but are not limited to (1) loss, or potential loss, of a safety or waste-isolation function to the extent that there is a reduction in the degree of protection provided to the public health and safety; (2) loss, or potential loss, of a safety or waste-isolation function to the extent that there is a reduction in the degree of protection provided for worker safety; (3) common-cause failures; and (4) any adverse quality trends. Additionally, repetitive conditions that are less significant but when taken collectively (1) indicate programmatic failure to properly implement the QA program, (2) may be precursors for a significant technical deficiency or problem or, (3) may reduce the margin of safety are considered to be significant conditions adverse to quality. (NQA-1-1983, Supplement S-1, Modified)

Site Characterization–The program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of the Yucca Mountain site, and the surrounding region to the extent necessary, relevant to the procedures under 10 CFR 63. Site characterization includes borings, surface excavations, excavation of the exploratory shafts and/or ramps, limited subsurface lateral excavations and borings, and in situ testing at a depth needed to determine the suitability of the site for a geologic repository. (10 CFR 63.2)

Software–Computer programs and associated documentation, and data pertaining to the operation of a computer system. (NQA-1-2000, Part I, Section 400)

Software Baseline–A specification or product that (i) has been formally reviewed and agreed upon, (ii) thereafter is the basis for further development, and (iii) can be changed only through formal change procedures.

Software Design Verification–The process of determining if the product of the software design activity fulfills the software design requirements. (NQA-1-2000, Subpart 2.7, Section 102)

Software Development Cycle–The activities that begin with the decision to develop a software product and end when the software is delivered. The software development cycle typically includes the following activities: (1) software design requirements, (2) software design, (3) implementation, (4) test, and sometimes (5) installation. (NQA-1-2000, Subpart 2.7, Section 102)

Software Engineering–(a) The application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software, that is, the application of engineering to software; and (b) the study of the approaches as in (a). (NQA-1-2000, Subpart 2.7, Section 102)

Software Item–Source code, object code, job control code, control data, or a collection of these items that function as a single unit. (IEEE Std. 610.12-1990)

Software Life Cycle–The activities that comprise the evolution of software from conception to retirement. The software life cycle typically includes the software development cycle phases and the activities associated with operation, maintenance, and retirement. (NQA-1-2000, Subpart 2.7, Section 102)

Software Life Cycle Element–A fundamental, constituent part of a life cycle phase. For example, the requirements phase consists of the individual requirements, the design phase consists of the individual design elements and the individual test cases, the implementation phase consists of source code and user instructions, and the testing phase consists of documented test results.

Software Operating Environment–A collection of software, firmware, and hardware elements that provide for the execution of computer programs. (NQA-1-2000, Subpart 2.7, Section 102)

Software Tool–A computer program used in the development, testing, analysis, or maintenance of a program or its documentation. Examples include comparators, cross-reference generators, compilers, Computer Aided Software Engineering (CASE) tools, configuration and code management software, decompilers, disassemblers, editors, flowcharts, monitor test case generators, and timing analyzers. (NQA-1-2000, Subpart 2.7, Section 102)

Software Validation–The testing and evaluation of completed software to ensure compliance with specified software requirements.

Software Verification–The process of determining whether or not the product(s) of a given phase of the software development cycle fulfills the requirements imposed by the previous phase. (IEEE Std. 610.12-1990, Modified)

Special Process–A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product. (NQA-1-1983, Supplement S-1)

Stop Work Order–A formal directive issued by management that work must be stopped until resolution of the related significant condition adverse to quality.

Substantial Safety Hazard–A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health or safety for any facility or activity licensed pursuant to 10 CFR 63. (10 CFR 21.3)

Supplier–Any individual or organization (except principal contractors) that furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

Support Software–Software that aids in the development and maintenance of other software (e.g., compilers, loaders, and other utilities), including software tools and system software. (IEEE Std. 610.12-1990)

Surveillance–The act of monitoring or observing to verify whether an item or activity conforms to specified requirements. (NQA-1-1983, Supplement S-1)

System Software–Software designed to enable the operation and maintenance of a computer system and its associated computer programs (e.g., operating systems, assemblers, and utilities). (NQA-1-2000, Subpart 2.7, Section 102)

Technical Assessment–When used for data qualification, an evaluation of the technical merit of unqualified data against established criteria.

Technical Report–As it pertains to scientific investigation, a document that presents scientific information such as data, analyses, interpretations, or conclusions.

Technical Specialist–An individual who is assigned to an audit team when the scope, complexity, or special nature of the work to be audited warrants assistance from a technical standpoint.

Test Case–A set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement. (NQA-1-2000, Subpart 2.7, Section 102)

Test Plan (procedure)–A document that describes the approach to be followed for testing a system or component. Typical contents identify items to be tested, tasks to be performed, and responsibilities for the testing activities. (NQA-1-2000, Subpart 2.7, Section 102)

Testing–An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions. (NQA-1-1983, Supplement S-1)

Testing (Software)–The process of operating a system (i.e., software and hardware) or system component under specified conditions, observing and recording the results, and making an evaluation of some aspect of the system (i.e., software and hardware) or system component in order to verify that it satisfies specified requirements and to identify errors. (NQA-1-2000, Subpart 2.7, Section 102)

Traceability–The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification. (NQA-1-1983, Supplement S-1)

Training–A systematic process provided to personnel so that they achieve proficiency, maintain proficiency, and adapt to changes in technology, methods, processes, or responsibilities as necessary to perform assigned tasks. (NQA-1-1989, Supplement 2S-4, Paragraph 4)

Transparent–A document sufficiently detailed as to purpose, method, assumptions, inputs, conclusions, references, and units such that a person technically qualified in the subject can understand the document and ensure its adequacy without recourse to the originator.

Unqualified Data (Existing Data)–

A. Unqualified data includes:

(i) Data developed prior to the implementation of a 10 CFR 60, Subpart G, or 10 CFR 63, Subpart G, Quality Assurance program, or

(ii) Data developed outside the Yucca Mountain Project, such as by oil companies, national laboratories, or universities, or

(iii) Data published in technical or scientific publications. (NUREG-1298, 2/88).

B. Unqualified data does not include established fact.

Use-As-Is–A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use. (NQA-1-1983, Supplement S-1)

Verification–The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. (NQA-1-1983, Supplement S-1)

Witness Point–A step in a document that requires notification to the specifying individual or organization that the activity is scheduled to take place. Work may proceed after notification.

Work–Activities that are subject to the *Quality Assurance Requirements and Description*.